

EPA Jacket 88783-3

Vol.2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 30, 2017

Leanne Pruett
Agent for Summit Agro USA, LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: Label Amendment – Add me-too use on apples
Product Name: Technical Sulfentrazone
EPA Registration Number: 88783-3
Application Date: May 26, 2017
Decision Number: 530227

Dear Ms. Pruett:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

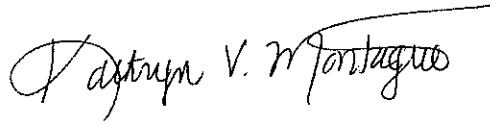
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 88783-3
Decision No. 530227

with FIFRA section 6. If you have any questions, please contact Mindy Ondish by phone at 703-605-0723, or via email at ondish.mindy@epa.gov.

Sincerely,

A handwritten signature in black ink, reading "Kathryn V. Montague". The signature is fluid and cursive, with a long horizontal line extending from the end of the name.

Kathryn Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

TECHNICAL SULFENTRAZONE
For Manufacturing of Herbicides

ACTIVE INGREDIENT	% BY WT
Sulfentrazone: N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide	94.0%
OTHER INGREDIENTS:	6.0%
TOTAL	100.0%

EPA Reg. No. 88783-3
EPA Est. No.

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Have person sip a glass of water if able to swallow.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Chemtrec at 1-800-424-9300 for emergency medical treatment information 24 hrs. a day.	

Manufactured For:
Summit Agro USA, LLC
240 Leigh Farm Rd., Suite 215
Durham, NC 27707

NET CONTENTS:

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System

(NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only For Formulation into Herbicides Intended For The Following Uses: Apples, Asparagus; Berry Crop group 13-07; *Brassica*, head and stem subgroup 5A; *Brassica*, leafy greens subgroup 5B; Cabbage; Citrus Crop Group 10; Dry Bean; Dry Pea; Corn, field, seed, and popcorn; Flax; Horseradish; Melon subgroup 9A; Mint; Vegetable, corn and tuberous subgroup 1C; Vegetable, fruiting subgroup 8-10; Okra; Peanuts; Pea, succulent; Pistachio; Rhubarb; Soybeans; Spring Wheat; Strawberry; Succulent Cowpea; Succulent Lima Bean; Sugarcane; Sunflower Subgroup 20B; Tobacco; Tree Nut Crop Group 14; Terrestrial Non-Crop Use; Tomato (transplanted only); Turf; Turnips; Vegetable Soybean (edamame).

This product may be used to formulate end use products for specific use(s) for which the formulator, user group, or grower has complied with USEPA data submission requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Store in original container only. Keep container closed when not in use.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on-site or at an approved waste disposal facility.

CONTAINER HANDLING: Plastic lined drums: Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into processing equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by State and local authorities. Offer the drum for recycling if available.

Supersack: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment; then dispose of empty bag in a sanitary landfill or by incineration, or by other procedures approved by state and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

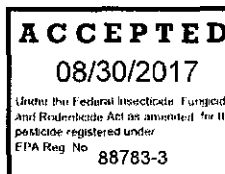
IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Summit Agro USA, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Summit Agro USA, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Summit Agro USA, LLC, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

[EPA Approval date]





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE: 439078; **Reg. No. /FILE SYMBOL No.:** 88783-3 (altCSF#3); **PRODUCT NAME:** Sulfentrazone Technical; **DECISION NO.:** 527309; **PC CODE(s):** 129081; **ACTION CODE:** R351; **FOOD USE:** Yes

DATE: August 15, 2017

SUBJECT: Product Chemistry Review of "Technical Sulfentrazone"

FROM: Shyam Mathur, Ph. D
Chemistry Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

SPB 8/15/17 *JK*

TO: Shanta Adeeb / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

REGISTRANT: Summit Agro USA, LLC
MRID Numbers: 50212201 and 50212202

INTRODUCTION:

Pyxis Regulatory Consulting Incorporation on behalf of the applicant Summit Agro USA., has submitted an application to amend the registration of the subject product. The amendment involved the submission of the alternate CSF #3 (dated March 13, 2017) representing a new producer, namely, [REDACTED]. The supporting group A product chemistry data has been submitted with MRID Nos. 50212201 and 50212202. The other currently approved sites are listed below:

Alternate CSF #2 (Dated 03-24-2016): Production site - [REDACTED]
[REDACTED]

Alternate CSF #1 (Dated 01-22-2015): Production site - [REDACTED]
[REDACTED]

Basic CSF (dated 07-12, 2012): Production site - [REDACTED]
[REDACTED]

CITAB has been asked to determine the acceptability of the proposed alt CSF #3 and the supporting product chemistry data.

DP BARCODE: 439078; Reg. No. /FILE SYMBOL No.: 88783-3 (altCSF#3); PRODUCT NAME: Sulfentrazone Technical; DECISION NO.: 527309; PC CODE(s): 129081; ACTION CODE: R351; FOOD USE: Yes

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550 (product identity & composition)

The submitted data are acceptable. Active ingredient and process-related impurities were adequately described (MRID No. 50212201 and alt CSF#3). The nominal concentration of the active ingredient in the proposed alt CSF #3 is 95.50% which is the average derived from the 5 batch preliminary analysis, and falls within the certified limits of the product label claim of 94%. The information presented meets the data requirements for 40CFR 158.320.

830.1600 (description of materials used to produce the product)

The product chemistry data submitted for the guideline 830.1600 (description of starting materials) are acceptable. The MSDSs of all the starting materials, and their suppliers and specifications are provided in the study with MRID 50212201. The information presented meets the data requirements for 40CFR 158.325.

830.1620 (description of production process)

The product chemistry data submitted data for the guideline 830.1620 (description of production process) are acceptable. Sulfentrazone technical was synthesized in [REDACTED]. The registrant has provided description of the production process, flow charts, chemical reactions pathways, and quality control measures were provided in MRID No. 50212201. The information presented meets the data requirements for 40CFR 158.330.

830.1670 (discussion on the formation of impurities)

The product chemistry data submitted for the guideline 830.1670 (discussion on the formation of impurities) are acceptable. Detailed information regarding the origins of impurities was provided (MRID No. 50212201). Potential impurities were identified and quantified as part of the five-batch analysis (MRID No. 50212202). The registrant has discussed the mechanism of the formation of the impurities identified in the technical product. The registrant has listed [REDACTED] impurities identified at the concentration of >0.1%. The registrant has mentioned that there are no impurities of tox concern present in the technical product. The information presented meets the data requirements for 40CFR 158.340.

830.1700 (preliminary analysis)

The submitted data are acceptable. Results are presented for a five-batch analysis of the active ingredient (MRID No. 50212202). The active ingredient sulfentrazone was identified by using HPLC-DAD-MS and identification confirmed by NMR, FTIR & UV-VIS spectroscopic validated method. The active ingredient sulfentrazone was determined by the validated analytical Method No. ABCTM-2016-66-06 (HPLC with UV detector operating at 245 nm & external calibration). The impurities in each of five batches of sulfentrazone technical were identified by comparing the reference item impurities with GC-MS and HPLC-MS. The test methods ABCTM-2016-66-03, ABCTM-2016-04 and ABCTM-2016-66-05 were employed to identify impurities in the test item. The test method ABCTH-2016-66-07 (HPLC-UV, 210nm) was fully validated with respect to specificity, linearity, precision, accuracy, LOQ & LOD for the quantitative of impurities. Details can be seen in the MRID 50212202. The data submitted satisfy the data requirements of 40CFR§158.345.

2

Manufacturing process information may be entitled to confidential treatment

DP BARCODE: 439078; **Reg. No. /FILE SYMBOL No.:** 88783-3 (altCSF#3); **PRODUCT NAME:** Sulfentrazone Technical; **DECISION NO.:** 527309; **PC CODE(s):** 129081; **ACTION CODE:** R351; **FOOD USE:** Yes

830.1750 (certified limits)

The product chemistry data submitted for the guideline 830.1750 satisfy the data requirements of 40CFR§158.350. The registrant has proposed the nominal concentration of 95.5% for the active ingredient sulfentrazone which falls within the certified limits of the product label claim nominal concentration 94.0%. The proposed upper and lower certified limits for the A.I. are based on the standard certified limits, whereas the certified limits for the impurities are based on 5 batch analysis.

830.1800 (enforcement analytical method)

The analytical method for quantifying the A.I. is HPLC-DAD (UV detector operating at 245 nm) with external standard calibration. The method was validated for selectivity, linearity, recovery, repeatability, LOD, LOQ (MRID No. 50212202). The information presented meets the data requirements for 40 CFR §158.355.

2. Group B guidelines (physical-chemical properties):

The group B product chemistry are not required for alternate CSF #3.

CONCLUSIONS:

The CITAB has reviewed the proposed alternate CSF #3 and the supporting group A data for "Sulfentrazone Technical" has concluded that:

1. The product chemistry data submitted for guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of the production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) are acceptable.
2. The proposed alternate CSF #3 (dated 03-13-2017; [REDACTED]) is acceptable and is supported by five batch analysis.

DP BARCODE: 439078; **Reg. No. /FILE SYMBOL No.:** 88783-3 (altCSF#3); **PRODUCT NAME:** Sulfentrazone Technical; **DECISION NO.:** 527309; **PC CODE(s):** 129081; **ACTION CODE:** R351; **FOOD USE:** Yes

830.1550. Product identity & composition: (MRID No. 50212202)

Active Ingredient: Sulfentrazone

Classification: Herbicide

Manufacturer:

Address:

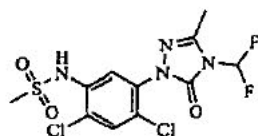
Chemical name (IUPAC): *N*-(2,4-Dichloro-5-[4-(difluoromethyl)-3-methyl-5-oxo-4,5-dihydro-1*H*-1,2,4-triazol-1-yl]phenyl)methanesulfonamide

CAS No.: 122836-35-5

Molecular Formula: C₁₁H₁₀Cl₂F₂N₄O₃S

Molecular Weight: 387.2

Structure Formula:



DP BARCODE: 439078; Reg. No. /FILE SYMBOL No.: 88783-3 (altCSF#3); PRODUCT NAME: Sulfentrazone Technical; DECISION NO.: 527309; PC CODE(s): 129081; ACTION CODE: R351; FOOD USE: Yes

Table 1. Manufacturing and Impurity Data for "Technical Sulfentrazone"				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	50212201	A	See summary of findings
830.1600	Description of materials used to produce the product	50212201	A	See summary of findings
830.1620	Description of production process	50212201	A	See summary of findings
830.1670	Discussion of formation of impurities	50212201	A	See summary of findings
830.1700	Preliminary analysis	50212202	A	See summary of findings
830.1750	Certified limits	Basic CSF (dated 03-13-17)	A	The NC of AI is 95.5% which falls within the certified limits of the product label claim NC of 94.%. The proposed upper & lower certified limits for the AI is based on the standard limits, whereas proposed limits for the impurities are based on the five batch analysis.
830.1800	Enforcement analytical method	50212202	A	See summary of findings
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

DP BARCODE: 439078; Reg. No. /FILE SYMBOL No.: 88783-3 (altCSF#3); . PRODUCT NAME: Sulfentrazone Technical; DECISION NO.: 527309; PC CODE(s): 129081; ACTION CODE: R351: FOOD USE: Yes

830.1800 (enforcement analytical method)
(MRID No. 50212202)

Determination of the AI by Analytical Method No. ABCTM-2016-66-06

Standard solution

In the 50 mL volumetric flasks transfer about 25 mg of Sulfentrazone Standard.

Dissolve and make up to the volume with acetonitrile.

Quality control solution

Quality control solution will be prepared as same as the standard solution preparation.

Sample solutions (duplicate for each batch)

In a 50 mL volumetric flask transfer about 25 mg, accurately weighed, of Test Item.

Dissolve and make up to the volume with acetonitrile.

Equipment

HPLC: Agilent 1200HPLC System with DAD

Column: Eclipse XDB-C18, 150 mm x 4.6 mm x 5 µm

HPLC Parameters

Mobile Phase: Phase A –Water (0.1% H₃PO₄)

Phase B –Methanol

Gradient: 0.00 min 75% Phase A : 25% Phase B

7.20 min 75% Phase A : 25% Phase B

7.30 min 5% Phase A : 95% Phase B

Flow Rate: 0.00 min 0.5 mL/min

7.20 min 0.5 mL/min

7.30 min 0.8 mL/min

Temperature: 30.0 °C

Signal: 245 nm

BW: 4 nm

Reference off

Spectrum Stored All

Injection Volume: 3 µL, Needle wash mode

Analysis Time: 10.0 min

Post Time: 5.0 min

Retention time of AI: about 8.6 minutes

Calculations

Calculate the Assay of the AI by the following equation:

$$W'' = \frac{A}{A'} \times W' \times P$$

$$\text{Active Ingredient (\%)} = \frac{W''}{W} \times 100$$

Where:

A is the average peak area of Active Ingredient in sample solution;

A' is the average peak area of Active Ingredient in Sulfentrazone Standard solution;

W is the mass of sample;

W' is the mass of Sulfentrazone Standard;

P is the purity of Sulfentrazone Standard.

Validation results are summarized below:

	Component	Active Ingredient
	Test Method	ABCTM-2016-66-06
Specificity Items	Resolution	2.80
	Tailing Factor	0.90
	Theoretical Plate Number	12045
	Peak Purity Factor	998.263
	Specificity	One Component
Linearity (n=7)	Correlation Coefficient	0.9998
	Slope	10.771
	y-Intercept	59.631
	Range (mg/L)	297.3 ~ 661.0
Precision (n=5)	RSD	0.27%
Accuracy (n=5)	Conc.(mg/L)	ca. 500
	Mean Recovery	99.57%
	RSD	0.87%

All of the validation data met the criteria, indicating that the analytical method for Active Ingredient, namely ABCTM-2016-66-06 was acceptable.

For more details, please refer to MRID No. 50212202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 31, 2017

Arianna Shorey
Regulatory Consultant
Summit Agro USA, LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: Notification per PRN 98-10 – Label updates including storage and disposal
Product Name: Technical Sulfentrazone
EPA Registration Number: 88783-3
Application Date: March 15, 2017
Decision Number: 527855

Dear Ms. Shorey:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, please contact Emily Schmid by phone at 703-347-0189, or via email at schmid.emily@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Emily Schmid" followed by a stylized flourish.

Kathryn V. Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

TECHNICAL SULFENTRAZONE
For Manufacturing of Herbicides

ACTIVE INGREDIENT

Sulfentrazone: N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide 94.0%

OTHER INGREDIENTS:

TOTAL

6.0%
100.0%

EPA Reg. No. 88783-3

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Have person sip a glass of water if able to swallow.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Chemtrec at 1-800-424-9300 for emergency medical treatment information 24 hrs. a day.	

Manufactured For:

Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

NET CONTENTS: 55.12 lb. (25 kg)

NOTIFICATION

88783-3

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

5/31/2017

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do

not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

% BY WT

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only For Formulation into Herbicides Intended For The Following Uses: Asparagus; Berry Crop group 13-07; Brassica, head and stem subgroup 5A; Brassica, leafy greens subgroup 5B; Cabbage; Citrus Crop Group 10; Dry Bean; Dry Pea; Corn, field, seed, and popcorn; Flax; Horseradish; Melon subgroup 9A; Mint; Vegetable, corn and tuberous subgroup 1C; Vegetable, fruiting subgroup 8-10; Okra; Peanuts; Pea, succulent; Pistachio; Rhubarb; Soybeans; Spring Wheat; Strawberry; Succulent Cowpea; Succulent Lima Bean; Sugarcane; Sunflower Subgroup 20B; Tobacco; Tree Nut Crop Group 14; Terrestrial Non-Crop Use; Tomato (transplanted only); Turt; Turnips; Vegetable Soybean (edamame).

This product may be used to formulate end use products that have specific for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and for uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Store in original container only. Keep container closed when not in use.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Plastic lined drums: Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into processing equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by State and local authorities. Offer the drum for recycling if available. **Supersack: Nonrefillable container.** Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or by other procedures approved by state and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Summit Agro USA, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Summit Agro USA, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Summit Agro USA, LLC, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

20140248[20170315]

resubmission

Schmid, Emily

From: Arianna Shorey <Arianna@PyxisRC.com>
Sent: Wednesday, May 31, 2017 3:30 PM
To: Schmid, Emily
Subject: RE: Label Notification (EPA Reg. No. 88783-3)
Attachments: 088783-3.20170531.Technical Sulfentrazone Label_clean.pdf;
088783-3.20170531.Technical Sulfentrazone Label_tracked.pdf

Hi Ms. Schmid,

Thank you for letting me know. Please find attached updated tracked and clean versions of the label. Please let me know if I can provide any additional information and thank you for your help.

Best,

Arianna

Arianna Shorey
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
T: (253) 853-7369
F: (253) 853-5516
E: Arianna@PyxisRC.com

From: Schmid, Emily [mailto:Schmid.Emily@epa.gov]
Sent: Wednesday, May 31, 2017 10:14 AM
To: Arianna Shorey <Arianna@PyxisRC.com>
Subject: Label Notification (EPA Reg. No. 88783-3)

Hi Arianna,

I am in the process of reviewing the label notification that you submitted for Technical Sulfentrazone (EPA Reg. No. 88783-3). To be consistent with the label review manual, could you change the container disposal instructions for the supersack to:

"Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration..."

Since this is such a small change, if you can just update the label and email the pdf to me, I can avoid turning this down and save some time.

Let me know if you have any questions.

Best regards,

Emily Schmid
Biologist
U.S. Environmental Protection Agency
Registration Division
Herbicide Branch



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 31, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MS. ARIANA SHOREY
PYXIS REGULATORY CONSULTING, INC.
SUMMIT AGRO USA, LLC
4110 136TH STREET CT NW
GIG HARBOR, WA 98332-

PRODUCT NAME: TECHNICAL SULFENTRAZONE
COMPANY NAME: SUMMIT AGRO USA, LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 88783-3
EPA RECEIPT DATE: 05/26/17

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 23, at (703) 305-1243.

Sincerely,

A handwritten signature in black ink, appearing to be "Sincerely," followed by a stylized signature.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
LEANNE@PYXISRC.COM

May 26, 2017

ELECTRONIC SUBMISSION

Kathryn Montague (PM23)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Summit Agro USA, LLC. – Technical Sulfentrazone (EPA Reg. No. 88783-3)
Label Amendment – addition of use site

Dear Ms. Montague,

On behalf of Summit Agro USA, LLC, I am submitting an application to amend the registration of Technical Sulfentrazone (EPA Reg. No. 88783-3), to add an additional use site (apples).

In support of this label amendment, the following documents are enclosed:

1. EPA Application Form 8570-1
2. Proposed Technical Sulfentrazone label with changes tracked
3. Proposed Technical Sulfentrazone label with changes incorporated
4. EPA Form 8570-34 (Certification with respect to Citation of Data)
5. EPA Form 8570-35 – Data Matrix – Agency Internal Copy and Public File Copy
6. Letter of Authorization

Because no data are being submitted with this amendment and no data will need to be reviewed to approve the proposed labeling, Summit believes this action is not subject to a Pesticide Registration Service Fee. If you have any questions or concerns regarding this application for registration, or require additional information, please contact me at (253) 853-7369 or Leanne@PyxisRC.com.

Best Regards,

P. Leanne Pruett
Pyxis Regulatory Consulting

Enclosures
cc: Summit Agro USA, LLC

DOCUMENT

**Environmental Protection Agency**United States
Washington, DC 20460

- ☐
- Registration
-
- ☒
- Amendment
-
- ☐
- Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 88783-3	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Summit Agro USA, LLC/Technical Sulfentrazone	PM# 23	
5. Name and Address of Applicant (include ZIP Code) Summit Agro USA, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 279-3149 Product Name Sulfentrazone Technical	

Section - II

<input checked="" type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Submission of an amended label to add additional use site (apples). As no data are being submitted with this amendment, nor will data need to be reviewed to approve the proposed labeling, Summit Agro USA, LLC believes this action is not subject to a Pesticide Registration Service Fee.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) PE lined fiberboard or metal drums		
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____	No. per container _____	If "Yes" Package wgt. _____	No. per container _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container _____		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name P. Leanne Pruett	Title Regulatory Consultant	Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant		
4. Typed Name P. Leanne Pruett	5. Date May. 26, 2017		



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
ARIANNA@PYXISRC.COM

March 15, 2017

ELECTRONIC DELIVERY

Kathryn Montague (PM 23)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Summit Agro USA, LLC– Technical Sulfentrazone (EPA Reg. No. 88783-3)
Revision to Storage and Disposal Instructions per PRN 2007-4

Dear Ms. Montague,

On behalf of Summit Agro USA, LLC please find the enclosed label notification revising the container disposal instructions per PRN 2007-4 for Technical Sulfentrazone (EPA Reg. No. 88783-3). The disposal section was revised to add the container handling instructions for supersack bags. In addition, the layout of the label has been changed to ensure that the Regions do not find the label out of compliance with the layout of the label on the product container.

In support of this notification, we submit the following documents:

1. Completed Application for Registration (EPA Form 8570-1)
2. One (1) copy of the label with changes tracked
3. One (1) copy of the label with changes incorporated
4. Letter of Authorization

Please feel free to contact me by phone (253) 853-7369 or by email at Arianna@PyxisRC.com if you have any questions or need any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Arianna Shorey".

Arianna Shorey

Enclosures

cc: Summit Agro USA, LLC



Environmental Protection Agency

Washington, DC 20460

United States

- ☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 88783-3	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Summit Agro USA, LLC / Technical Sulfentrazone	PM# PM 23	
5. Name and Address of Applicant (include ZIP Code) Summit Agro USA, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ☐ Amendment – Explain below. ☐ Final printed labels in response to Agency letter dated _____
- ☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application.
- ☒ Notification – Explain below. ☐ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) PE lined fiberboard or metal drums or supersacks
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 110, 55, 1102 lbs	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Arianna Shorey	Title Regulatory Consultant	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant	
4. Typed Name Arianna Shorey	5. Date Mar. 15, 2017	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D439078; **FILE SYMBOL No.:** 88783-3 (altCSF#3 screen); **PRODUCT NAME:** Technical Sulfentrazone; **DECISION No.:** 527309; **PC Code(s):** 129081; **ACTION CODE:** R351;
FOOD Use: Yes

DATE OUT: April 10, 2017

SUBJECT: 45/90-day screen for technical product: "Technical Sulfentrazone"

FROM: Shyam Mathur, Chemistry Team Leader, CITAB / RD (7505P)

TO: Shanda Adeeb / Kathryn Montague, RM 23; Herbicide Branch / RD (7505P)

Company Name: Summit Agro USA LLC
Active Ingredient(s): Sulfentrazone (95.5%)
MRID No(s): 50212201 & 50212202

CONCLUSION:

Deficiencies: No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

Group A: All required data submitted

Group B: All required data submitted

CSF: Proposed alternate CSF #3 (dated 03-13-2017; [REDACTED])

PRODUCT LABEL: Not Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



Receipt for Section 3

S: 1000739

Milestone Email: Ann@PyxisRC.com

Regulatory Type: Product Registration - Section 3



Resubmission: ☐ Yes ☒ No

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No



Print Letter

Enter More Information

Tracking

Application Type: Amendment



Company: 88783 SUMMIT AGRO USA, LLC

Risk Manager: Registration Division, Risk Management Team 23



Product #: 88783-3

Product Name: TECHNICAL SULFENTRAZONE

Override#:

Me Too
Section3:

Me Too Product
Name:

Application Date: 15-Mar-2017



OPP Rec'd Date: 15-Mar-2017



Front End Date: 16-Mar-2017



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track ☐

New Ingredient: ☐

Receipt Description:

Portal submission pkg #18115 Amendment to add an unregistered source of active ingredient.

New Ingredient

Request Date:

New Ingredient

Received Date

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Study

CSF

View/Edit

De



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 22, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH STREET CT NW
GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 15-MAR-17. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
ANN@PYXISRC.COM

MRID 502122-00

March 15, 2017

ELECTRONIC SUBMISSION

Kathryn Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Summit Agro USA, LLC
Technical Sulfentrazone (EPA Reg. No. 88783-3)
Application to Add Alternate Source of Active Ingredient
PRIA Category R351

Dear Ms. Montague:

On behalf of Summit Agro USA, LLC, we are submitting an application to amend the registration of Technical Sulfentrazone to add an alternate source of the active ingredient, sulfentrazone. In support of this application, we submit the following documents:

1. Application for a Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula for Alternate #4 (EPA Form 8570-4) dated March 13, 2017
3. Certification with Respect to Citation of Data (EPA Form 8570-34)
4. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
5. Public File Copy of the Data Matrix (EPA Form 8570-35)
6. Copy of PRIA payment
7. Letter of Authorization
8. Product Specific Data:

MRID	Guideline Number	Study Title
50212201	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for Technical Sulfentrazone. <i>Contains Confidential Business Information.</i>
50212202	830.1700, 830.1800	Zhang, Y. Five Batch Analysis of Sulfentrazone TGAI - Validation of Analytical Methodology for the Assay of Active Ingredient and Impurities in Sulfentrazone TGAI and Subsequent 5-Batch Analysis of the Test Item. <i>Contains Confidential Business Information.</i>

Summit Agro USA, LLC is using the selective method of data support. As per EPA's interpretation of 40 CFR 152.93(b)(2)(i), Summit Agro USA, Inc. submitted notices of intent to apply and offers to pay to the extent required by FIFRA § 3(c)(1)(F). This action falls under PRIA category R351 (54: Amendment requiring data review within RD; add source of active ingredient). The fee for this action is \$13,226 and has been paid.

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

Ann M. Tillman, Agent
Summit Agro USA, LLC

Enclosures

Memorandum**E-SUBMISSION**Date: 3 / 22 / 17To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 21, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-527309
EPA File Symbol or Registration Number: 88783-3
Product Name: TECHNICAL SULFENTRAZONE
EPA Receipt Date: 15-Mar-2017
EPA Company Number: 88783
Company Name: SUMMIT AGRO USA, LLC

MS. ANN TILLMAN
PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH STREET CT NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0510.

Sincerely,

A handwritten signature in black ink, appearing to be "J. [unclear]".

Front End Processing Staff
Information Technology & Resources Management Division

{1000739R~

37

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3-15-17

Experts In-Processing Signature: B. B. Date 3-21-17 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>88783-3</u>		EPA Receipt Date: <u>3-15-17</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>No inerts to review</u>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and guidance is available)					X
7	Is the data package consistent with <u>PR Notice 86-5</u>			X		
8	<u>Notice of Filing</u> included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass
 - Required forms are complete.
 Alerts: Pass
 - No alerts to review, Technical and impurities only.

PRN 11-3: Pass
 MRID-502122

AN 3/22/17

Overall Status: Pass

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Summit Agro USA, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136 th St. Ct. NW, Gig Harbor, WA 98332 (253) 853-7369	EPA Registration Number/File Symbol/ 88783-3
Active Ingredient(s) and/or representative test compound(s) sulfentrazone	Date Mar. 15, 2017
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TGAI	Product Name Technical Sulfentrazone

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statements (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have including with this form a list of companies send offer of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (II) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Ann M. Tillman

Date

Mar. 15, 2017

Typed or Printed Name and Title

Ann M. Tillman | Agent



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
ANN@PYXISRC.COM

MRID 502122-00

March 15, 2017

ELECTRONIC SUBMISSION

Kathryn Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Summit Agro USA, LLC
Technical Sulfentrazone (EPA Reg. No. 88783-3)
Application to Add Alternate Source of Active Ingredient
PRIA Category R351

Dear Ms. Montague:

On behalf of Summit Agro USA, LLC, we are submitting an application to amend the registration of Technical Sulfentrazone to add an alternate source of the active ingredient, sulfentrazone. In support of this application, we submit the following documents:

1. Application for a Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula for Alternate #4 (EPA Form 8570-4) dated March 13, 2017
3. Certification with Respect to Citation of Data (EPA Form 8570-34)
4. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
5. Public File Copy of the Data Matrix (EPA Form 8570-35)
6. Copy of PRIA payment
7. Letter of Authorization
8. Product Specific Data:

MRID	Guideline Number	Study Title
50212201	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for Technical Sulfentrazone. <i>Contains Confidential Business Information.</i>
50212202	830.1700, 830.1800	Zhang, Y. Five Batch Analysis of Sulfentrazone TGAI - Validation of Analytical Methodology for the Assay of Active Ingredient and Impurities in Sulfentrazone TGAI and Subsequent 5-Batch Analysis of the Test Item. <i>Contains Confidential Business Information.</i>

Summit Agro USA, LLC is using the selective method of data support. As per EPA's interpretation of 40 CFR 152.93(b)(2)(i), Summit Agro USA, Inc. submitted notices of intent to apply and offers to pay to the extent required by FIFRA § 3(c)(1)(F). This action falls under PRIA category R351 (54: Amendment requiring data review within RD; add source of active ingredient). The fee for this action is \$13,226 and has been paid.

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

Ann M. Tillman, Agent
Summit Agro USA, LLC

Enclosures

**Environmental Protection Agency**United States
Washington, DC 20460

- ☐
- Registration
-
- ☒
- Amendment
-
- ☐
- Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 88783-3	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Summit Agro USA, LLC/Technical Sulfentrazone	PM# 23	
5. Name and Address of Applicant (include ZIP Code) Summit Agro USA, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Amendment to add an unregistered source of active ingredient. PRIA Category R 351.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) PE lined fiberboard or metal drums		
* Certification must be submitted	If "Yes" Unit Packaging wgt. _____	No. per container _____	If "Yes" Package wgt. _____	No. per container _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1102, 55 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Ann M. Tillman		Title Regulatory Consultant		Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Ann M. Tillman		5. Date Mar. 15, 2017			

From: notification@pay.gov
To: [Ann Tillman](#)
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
Date: March 13, 2017 6:53:45 PM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 26181JFS
Agency Tracking ID: 75203926837
Transaction Type: Sale
Transaction Date: 03/13/2017 06:53:40 PM EDT

Account Holder Name: Susan Hill

Transaction Amount: \$13,226.00
Card Type: Visa
Card Number: *****4824

Registration Number: 88783-3
Company Name: Summit Agro USA LLC
Company Number: 88783
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



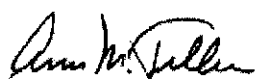
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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 1 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	50212201	Summit Agro USA, LLC	OWN	
		49885301	Summit Agro USA, LLC	OWN	
		49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	50212201	Summit Agro USA, LLC	OWN	
		49885301	Summit Agro USA, LLC	OWN	
		49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	
830.1620	Description of Production Process	50212201	Summit Agro USA, LLC	OWN	
		49885301	Summit Agro USA, LLC	OWN	
		49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	50212201	Summit Agro USA, LLC	OWN	
		49885301	Summit Agro USA, LLC	OWN	
		49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 2 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1700	Preliminary Analysis	50212202	Summit Agro USA, LLC	OWN	
		49885302	Summit Agro USA, LLC	OWN	
		49059002	Tagros Chemicals India Ltd.	PER	
		48890702	Summit Agro USA, LLC	OWN	
830.1750	Certified Limits	50212201	Summit Agro USA, LLC	OWN	
		49885301	Summit Agro USA, LLC	OWN	
		49059002	Tagros Chemicals India Ltd.	PER	
		49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	
830.1800	Enforcement Analytical Method	50212202	Summit Agro USA, LLC	OWN	
		49885302	Summit Agro USA, LLC	OWN	
		49059002	Tagros Chemicals India Ltd.	PER	
		48890702	Summit Agro USA, LLC	OWN	
		48890703	Summit Agro USA, LLC	OWN	
830.6302	Color	48890704	Summit Agro USA, LLC	OWN	
830.6303	Physical State	48890704	Summit Agro USA, LLC	OWN	
830.6304	Odor	48890704	Summit Agro USA, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	48890704	Summit Agro USA, LLC	OWN	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 3 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/Reduction: Chemical Incompatibility	48890704	Summit Agro USA, LLC	OWN	
830.6315	Flammability	48890705	Summit Agro USA, LLC	OWN	Waiver ²
830.6316	Explosibility	48890705	Summit Agro USA, LLC	OWN	Waiver ³
830.6317	Storage Stability	49267701	Summit Agro USA, LLC	OWN	
830.6319	Miscibility				Not required ⁴
830.6320	Corrosion Characteristics	49267701	Summit Agro USA, LLC	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁵
830.7000	pH	48890704	Summit Agro USA, LLC	OWN	
830.7050	UV/Visible Absorption	48890704	Summit Agro USA, LLC	OWN	
830.7100	Viscosity				Not required ⁶
830.7200	Melting Point/Melting Range	48890704	Summit Agro USA, LLC	OWN	
830.7220	Boiling Point/Boiling Range				Not required ⁷
830.7300	Density/Relative Density/Bulk Density	48890704	Summit Agro USA, LLC	OWN	
830.7370	Dissociation Constants in Water	48890704	Summit Agro USA, LLC	OWN	
830.7520	Particle size, fiber length, diameter distribution	48890705	Summit Agro USA, LLC	OWN	Waiver ⁸
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				See 830.7570
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7570

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 4 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	48890704	Summit Agro USA, LLC	OWN	
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	48890704	Summit Agro USA, LLC	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	48890704	Summit Agro USA, LLC	PL	
870.1100 (81-1)	Acute Oral Toxicity: Rat	41911605 41911606		OLD OLD	See endnote ⁹
870.1200 (81-2)	Acute Dermal Toxicity: Rat	41911607		OLD	See endnote ¹⁰
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	42471002		OLD	See endnote ¹¹
870.2400 (81-4)	Primary Eye Irritation: Rabbit	41911608		OLD	See endnote ¹²
870.2500 (81-5)	Primary Dermal Irritation	41911609		OLD	See endnote ¹³
870.2600 (81-6)	Dermal Sensitization	41911610		OLD	See endnote ¹⁴
Generic Data Requirements					
850.2100	Acute Avian Oral Toxicity	41911617		OLD	See endnote ¹⁵
850.2200	Acute Avian Dietary Toxicity	41911618 41911619		OLD OLD	See endnote ¹⁶
850.2400	Wild Mammal Toxicity				Not required

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017




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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 5 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2300	Avian Reproductive Toxicity	43355901 43355902		OLD OLD	See endnote ¹⁷
850.2500	Simulated or Actual Field Testing				Not required
850.1075	Freshwater Fish Toxicity	41911620 41911621		OLD OLD	See endnote ¹⁸
850.1010	Freshwater Invertebrate Toxicity	41911622		OLD	See endnote ¹⁹
850.1025, 850.1035, 850.1045, 850.1055, 850.1075	Acute Toxicity Estuarine and Marine Organisms	43588602 44054901 43588603		OLD OLD OLD	See endnote ²⁰
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	43588605		OLD	See endnote ²¹
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)				Not required
850.1400	Fish Early Life Stage (Freshwater)	43588604		OLD	See endnote ²²
850.1400	Fish Early Life Stage (Saltwater)				Not required
850.1500	Life Cycle Fish				Not required
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	43345433		OLD	Not required ²³
850.1950	Simulated or Actual Field Testing for Aquatic Organisms				Not required

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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DATA MATRIX

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1735	Whole Sediment: Acute Freshwater Invertebrates				Not required
850.1740	Whole Sediment: Acute Marine Invertebrates				Not required
N/A	Whole Sediment: Chronic Invertebrates Freshwater and Marine				Not required
850.3020	Honeybee Acute Contact Toxicity	44054902		OLD	See endnote ²⁴
850.3030	Honeybee Toxicity of Residues on Foliage				Not required
850.3040	Field Testing for Pollinators				Not required
870.6100	Delayed Neurotoxicity (Acute) – Hen				Not required
870.6200	Acute Neurotoxicity – Rat	43345405		OLD	See endnote ²⁵
870.3100	90-Day Oral: Rodent	43004601		OLD	See endnote ²⁶
870.3150	90-Day Oral: Non-Rodent	42932102		OLD	See endnote ²⁷
870.3200	21/28-Day Dermal Toxicity	44248301		OLD	See endnote ²⁸
870.3250	90-Day Dermal Toxicity				Not required
870.3465	90-Day Inhalation Toxicity	49253902	FMC Corporation	PAY	
870.6100	28-Day Delayed Neurotoxicity Hen				Not required
870.6200	90-Day Neurotoxicity	44215701		OLD	See endnote ²⁹
870.4100	Chronic Oral Rodent	43345409		OLD	See endnote ³⁰

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 7 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.4200	Carcinogenicity	43345409 43345407		OLD OLD	See endnote ³¹
870.3700	Reproduction/Developmental Toxicity Screening Test	42932105 42932106		OLD OLD	See endnote ³²
870.3800	2-Generation Reproduction: Rat	43345408 43869101		OLD OLD	See endnote ³³
870.6300	Developmental Neurotoxicity Study				Not required
870.5100	Bacterial Reverse Mutation Test	41911611		OLD	See endnote ³⁴
870.5300, 830.5375	<i>In vitro</i> Mammalian Cell Assay	43004604		OLD	See endnote ³⁵
870.5385, 870.5395, 870.5450	<i>In vivo</i> Cytogenetics	43004605 44248302		OLD OLD	See endnote ³⁶
870.7485	Metabolism and Pharmacokinetics	43345410		OLD	See endnote ³⁷
870.7200	Companion Animal Safety				Not required
870.7600	Dermal Penetration				Not required
870.7800	Immunotoxicity	48748601	FMC Corporation	PAY	See endnote ³⁸
875.1100	Dermal Exposure – Outdoor		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1200	Dermal Exposure - Indoor				Not required

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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 8 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1300	Inhalation Exposure – Outdoor		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1500	Biological Monitoring		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1600	Data Reporting and Calculations		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1700	Product Use Information				Not required

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues	44802601		OLD	
		45005901		OLD	
		45005902		OLD	
		45005903		OLD	
		45005904		OLD	
		45005905		OLD	
		45005906		OLD	
		45005907		OLD	
		45005908		OLD	
		45005909		OLD	
		45005910		OLD	
		45005911		OLD	
		45138201		OLD	
		45138202		OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	45175101		OLD	
		45175102		OLD	
		45175103		OLD	
		45175104		OLD	
		45175105		OLD	
		45191701		OLD	
		45224801		OLD	
		45344501		OLD	
		45432301		OLD	
		45432302		OLD	
		45432303		OLD	
		45469501		OLD	
		45469502		OLD	
		45480301		OLD	
		45480302		OLD	
		45491901		OLD	
		45491902		OLD	
		45491903		OLD	
		45491904		OLD	
		45491905		OLD	

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	45530101		OLD	
		45530102		OLD	
		45530103		OLD	
		45574001		OLD	
		45726301	Agricultural Reentry Task Force	PAY	
		45726302	Agricultural Reentry Task Force	PAY	
		46040301	Agricultural Reentry Task Force	PAY	
		46040302	Agricultural Reentry Task Force	PAY	
		46405901	Agricultural Reentry Task Force	PAY	
		46513901	Agricultural Reentry Task Force	PAY	
		46734001	Agricultural Reentry Task Force	PAY	
		46734002	Agricultural Reentry Task Force	PAY	
		46789301	Agricultural Reentry Task Force	PAY	
		46789302	Agricultural Reentry Task Force	PAY	
		48866801	Agricultural Reentry Task Force	PAY	
		49157401	Agricultural Reentry Task Force	PAY	
		49157402	Agricultural Reentry Task Force	PAY	
		49299201	Agricultural Reentry Task Force	PAY	
		49309201	Agricultural Reentry Task Force	PAY	
		44972201		OLD	

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	44972202		OLD	
		44972203		OLD	
		44972204		OLD	
		44972205		OLD	
		44972206		OLD	
		44972207		OLD	
		44983501		OLD	
		45262901		OLD	
		45262902		OLD	
		45663701	Outdoor Residential Exposure TF	PAY	
		45663702	Outdoor Residential Exposure TF	PAY	
		45663703	Outdoor Residential Exposure TF	PAY	
		46042401	Outdoor Residential Exposure TF	PAY	
		46042402	Outdoor Residential Exposure TF	PAY	
		46190501	Outdoor Residential Exposure TF	PAY	
875.2200	Soil Residue Dissipation				See 875.2100
875.2400	Dermal Exposure				See 875.2100
875.2500	Inhalation Exposure				See 875.2100
875.2600	Biological Monitoring				Not required
875.2700	Product Use Information				Not required
875.2800	Descriptions of Human Activity				Not required

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2900	Data Reporting and Calculations				Not required
875.3000	Nondietary Ingestion Exposure				Not required
201-1	Droplet Size Spectrum	42565901 42608401 42907401 43254001 43485601 43485602 43485603 43485604 43493801 43493802 43508001 43535801 43535802 43657601		OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD	

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet Size Spectrum (cont'd)	43657602		OLD	
		43665401		OLD	
		43665402		OLD	
		43757801		OLD	
		43757802		OLD	
		43766501		OLD	
		43766502		OLD	
		43766503		OLD	
		43766503		OLD	
		43766504		OLD	
		43781101		OLD	
		43803501		OLD	
		43832101		OLD	
		43832102		OLD	
		43845501		OLD	
		43845901		OLD	
		43925701		OLD	
		43953001		OLD	
		43953002		OLD	
		44010201		OLD	

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet size spectrum (cont'd)	44070001		OLD	
		44100901		OLD	
		44134101		OLD	
		44178701		OLD	
		44310401		OLD	
		44640801		OLD	
		44640901		OLD	
		44641001		OLD	
		44696901		OLD	
		44747401		OLD	
		44763001		OLD	
		44878601		OLD	
		44908901		OLD	
202-1	Droplet Size Spectrum				See 201-1
850.4100	Tier 1: Seedling Emergence	43345411 43783601		OLD OLD	See endnote ⁴⁰
850.4150	Tier 1: Vegetative Vigor	43345412 43783602		OLD OLD	See endnote ⁴¹

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400, 850.5400	Tier 1: Aquatic Plant Growth	43345413		OLD	See endnote ⁴²
		43651006		OLD	
		43651007		OLD	
		43651004		OLD	
		43651005		OLD	
850.4100	Tier 2: Seedling Emergence	43345411 43783601		OLD OLD	See endnote ⁴³
850.4150	Tier 2: Vegetative Vigor	43345412 43783602		OLD OLD	See endnote ⁴⁴
850.4400, 850.5400	Tier 2: Aquatic Plant Growth	43345413		OLD	See endnote ⁴⁵
		43651006		OLD	
		43651007		OLD	
		43651004		OLD	
		43651005		OLD	
850.4300	Terrestrial Field				Not required
850.4450	Aquatic Field				Not required
850.4025	Target Area Phytotoxicity				Not required

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120	Hydrolysis	41928202		OLD	See endnote ⁴⁶
835.2240	Photodegradation in Water	43588601		OLD	See endnote ⁴⁷
835.2410	Photodegradation in Soil	43345425		OLD	See endnote ⁴⁸
835.2370	Photodegradation in Air				Not required
835.4100	Aerobic Soil Metabolism	41928203 42932117		OLD OLD	See endnote ⁴⁹
835.4200	Anaerobic Soil Metabolism				Not required ⁵⁰
835.4300	Aerobic Aquatic Metabolism	43345426		OLD	See endnote ⁵¹
835.4400	Anaerobic Aquatic Metabolism			GAP	See endnote ⁵²
835.1230	Leaching/Adsorption/Desorption	43355903		OLD	See endnote ⁵³
835.1410	Volatility – Laboratory				Not required
835.8100	Volatility – Field				Not required
835.6100	Soil Field Dissipation Study	43345427 43651009 43651008 43345434		OLD OLD OLD OLD	
835.6200	Aquatic Sediment Field Dissipation Study				Not required
835.6300	Forest Field Dissipation Study				Not required

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6400	Combination and Tank Mixes				
835.7100	Ground Water Monitoring	46816001 47453601 47453602 43345434 43926814	FMC Corporation FMC Corporation FMC Corporation	PAY PAY PAY OLD OLD	See endnote ⁵⁴
850.6100	Environmental Chemistry Methods	48649401 48649402 48649403	FMC Corporation FMC Corporation FMC Corporation	PAY PAY PAY	
860.1300	Nature of the Residue: Plants	42932107 43656501 48397302 48397303 48397304	FMC Corporation FMC Corporation FMC Corporation	OLD OLD PAY PAY PAY	
860.1300	Nature of the Residue: Livestock	43345414 43345415		OLD OLD	

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1850	Confined Rotational Crops	43761702		OLD	
		43345428		OLD	
		44450201		OLD	

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Residue Analytical Methods	44450202		OLD	
		42932111		OLD	
		42932110		OLD	
		42932109		OLD	
		42932108		OLD	
		43278201		OLD	
		43651015		OLD	
		43651014		OLD	
		43761703		OLD	
		43761704		OLD	
		43761705		OLD	
		43926813		OLD	
		43926806		OLD	
		43953801		OLD	
		44005602		OLD	
		44005601		OLD	
		44118802		OLD	
		44118801		OLD	
		44450202		OLD	

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1360	Multiresidue Method	43345417		OLD	
		43345416		OLD	
		43651013		OLD	
860.1380	Storage Stability	42932112		OLD	
		42932113		OLD	
		43345418		OLD	
		43345419		OLD	
		43345420		OLD	
		43345421		OLD	
		43761706		OLD	
		43926812		OLD	
		43926811		OLD	
860.1500	Magnitude of the Residue in Plants: Asparagus	45752601	IR-4	PUBLIC	
		48397309		PAY	
		47311401		PUBLIC	
860.1500	Magnitude of the Residue in Plants: Berry (group 13-07)	47311402	IR-4	PUBLIC	
		45393501		OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 22 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: Citrus	48397308	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Corn	45567402		OLD	
860.1500	Magnitude of the Residue in Plants: Flax	47311407	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Horseradish	45393502		OLD	
860.1500	Magnitude of the Residue in Plants: Melon	47311403	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Mint	45393503		OLD	
860.1500	Magnitude of the Residue in Plants: Vegetable, corn and tuberous subgroup 1C	45582201		OLD	
860.1500	Magnitude of the Residue in Plants: Fruiting Vegetable	47311404 47311405	IR-4 IR-4	PUBLIC PUBLIC	
860.1500	Magnitude of the Residue in Plants: Peanuts	45077902		OLD	
860.1500	Magnitude of the Residue in Plants: Peas and Beans	45567404 47311406	 IR-4	OLD PUBLIC	
860.1500	Magnitude of the Residue in Plants: Pistachio	48397306	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Rhubarb	48514802	IR-4	PUBLIC	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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DATA MATRIX

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: Soybeans	42932114 42932115 43278202 43345422 43345423 44118803		OLD OLD OLD OLD OLD OLD	
860.1500	Magnitude of the Residue in Plants: Wheat	48514803	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Strawberry	47311408	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Sugarcane	45077904		OLD	
860.1500	Magnitude of the Residue in Plants: Sunflower (Subgroup 20B)	45096501		OLD	
860.1500	Magnitude of the Residue in Plants: Tobacco	44248401 44248402 44248403		OLD OLD OLD	
860.1500	Magnitude of the Residue in Plants: Tree Nuts	48397306	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Turnip	48514801	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Citrus	48397308	FMC Corporation	PAY	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Magnitude of the Residue in Processed Food or Feed: Corn	45567403		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Flax	47311407	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Mint	45393503		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Vegetable, corn and tuberous subgroup 1C	45582201		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Fruiting Vegetable	47311404	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Peanuts	45077903		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Soybeans	42932116 43278202		OLD OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Wheat	48514803	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Sugarcane	45077905		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Sunflower (Group 20B)	45096501		OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 25 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1480	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs				Not required
860.1400	Nature and Magnitude of the Residue in Potable Water				Not required
860.1400	Magnitude of the Residue in Fish				Not required
860.1400	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water				Not required
860.1460	Magnitude of the Residue in Food Handling Establishments				Not required

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1900	Field Rotational Crops	43926803		OLD	
		43926804		OLD	
		43926805		OLD	
		43926807		OLD	
		43926808		OLD	
		43926809		OLD	
		43926810		OLD	
		44450203		OLD	
		44450205		OLD	
		44450206		OLD	
		44118807		OLD	
		44118806		OLD	
		43651012		OLD	
		44118805		OLD	
		43345431		OLD	
		44118804		OLD	
		43651010		OLD	
		44450204		OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017

Endnotes for Data Matrix for Technical Sulfentrazone

-
- ¹ **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- ² **830.6315** - Summit Agro USA, LLC requested a waiver from this data requirement because Technical Sulfentrazone is a solid and is not expected to be flammable. EPA accepted this waiver.
- ³ **830.6316** - Summit Agro USA, LLC requested a waiver from this data requirement because sulfentrazone does not have the chemical bonds or functional groups associated with explosive chemicals. EPA accepted this waiver.
- ⁴ **830.6319** - This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Technical Sulfentrazone is a technical material that is a solid and is not to be diluted with petroleum solvents. This data requirement is not applicable to Technical Sulfentrazone.
- ⁵ **830.6321** - These data are not required unless the product is an end-use product. Technical Sulfentrazone is a technical grade material and this data requirement is not applicable.
- ⁶ **830.7100** - This requirement is not applicable to Technical Sulfentrazone because it is a solid.
- ⁷ **830.7220** - This requirement is not applicable to Technical Sulfentrazone because it is a solid. The melting point of Technical Sulfentrazone was determined and that data is presented in MRID 48890704.
- ⁸ **830.7520** - A waiver was submitted by Summit Agro USA, LLC for this data requirement for Technical Sulfentrazone because it is not a fibrous material and is not a water-insoluble material. EPA accepted this waiver.
- ⁹ **870.1100** - The study cited is listed in the June 5, 2014 Preliminary Human Health Risk Assessment for Registration Review (Human Health Risk Assessment, DP Barcode D410365) as satisfying the data requirement. Note MRID 41911606 was also listed under 870.1200, but this appears to be an acute oral study. As such, MRID 41911606 is also cited under 870.1100.
- ¹⁰ **870.1200** - MRID numbers 41911606 and 42286400 were listed in the Human Health Risk Assessment as satisfying this data requirement. However, MRID number 41911606 appears to correspond to an acute oral study (see 870.1100) and 42286400 appears to be a transmittal document for a response for a dermal sensitization study. Because neither of these citations correspond to an acute dermal study, MRID number 41911607 is cited.
- ¹¹ **870.1300** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹² **870.2400** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹³ **870.2500** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹⁴ **870.2600** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹⁵ **850.2100** - The study cited is listed in the June 11, 2014 Preliminary Ecological Risk Assessment for Registration Review (Ecological Risk Assessment, DP Barcode D409753) as satisfying the data requirement.
- ¹⁶ **850.2200** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ¹⁷ **850.2300** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ¹⁸ **850.1075** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.

Endnotes for Data Matrix for Technical Sulfentrazone

- ¹⁹ **850.1010** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²⁰ **850.1025, 850.1035, 850.1045, 850.1055, 850.1075** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²¹ **850.1300** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²² **850.1400** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²³ **850.1710, 850.1730, 850.1850** – Although based on the Koc, these data are not typically required, MRID 43345433 is cited. This study was identified as acceptable in the June 11, 2014 Ecological Risk Assessment.
- ²⁴ **850.3020** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. MRID number 43678166 is also listed in the Ecological Risk Assessment, but this study appears to correspond to an azoxystrobin study submitted by Syngenta, not a sulfentrazone study. As such, MRID 43678166 is not cited.
- ²⁵ **870.6200** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁶ **870.3100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁷ **870.3150** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁸ **870.3200** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁹ **870.6200** – MRID 43345405 is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement. However, this citation corresponds to an acute neurotoxicity study. Therefore, MRID 44215701, a subchronic neurotoxicity study with sulfentrazone is cited.
- ³⁰ **870.4100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³¹ **870.4200** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³² **870.3700** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³³ **870.3800** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁴ **870.5100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁵ **870.5300, 830.5375** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁶ **870.5385, 830.5395, 870.5450** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁷ **870.7485** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁸ **870.7800** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.

Endnotes for Data Matrix for Technical Sulfentrazone

- ³⁹ **875.1100, 875.1300, 875.1500, 875.1600** – Summit Agro USA, LLC is a “Participating Company” in good standing with the Agricultural Handlers Exposure Task Force (AHETF). Data submitted by the AHETF satisfy this data requirement. A letter of authorization for reliance on AHETF data can be provided upon request.
- ⁴⁰ **850.4100** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783601, supplement to 43345411, is also cited.
- ⁴¹ **850.4150** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783602, supplement to 43345412, is also cited.
- ⁴² **850.4400, 850.5400** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: although MRID 43651006 was classified as supplemental, EPA did not require this study to be replaced and relied on it for registration review purposes.
- ⁴³ **850.4100** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783601, supplement to 43345411, is also cited.
- ⁴⁴ **850.4150** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783602, supplement to 43345412, is also cited.
- ⁴⁵ **850.4400, 850.5400** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: although MRID 43651006 was classified as supplemental, EPA did not require this study to be replaced and relied on it for registration review purposes.
- ⁴⁶ **835.2120** – The study cited is listed in the Sept. 9, 2009 EFED Problem Formulation for Registration Review (Problem Formulation) as satisfying the data requirement.
- ⁴⁷ **835.2240** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁴⁸ **835.2410** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁴⁹ **835.4100** – The studies cited are listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement. Note: it appears MRID 41922803 was listed in error and that the correct MRID should be 41928203 and is cited herein.
- ⁵⁰ **835.4200** – The study submitted was not considered acceptable in the June 11, 2014 Ecological Risk Assessment, but EPA notes that this is “not a required study” (page 31). Therefore, no data are cited here.
- ⁵¹ **835.4300** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁵² **835.4400** – The study submitted was not considered acceptable in the June 11, 2014 Ecological Risk Assessment and EPA requested the submission of additional data to satisfy the data requirement. Therefore, this data requirement is identified as “data gap.”
- ⁵³ **835.1230** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁵⁴ **835.7100** – The studies cited were listed in the June 11, 2014 Ecological Risk Assessment.



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Date: March 13, 2017

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Tagros Chemicals India Ltd.	PER	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Tagros Chemicals India Ltd.	PER	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Tagros Chemicals India Ltd.	PER	
			Summit Agro USA, LLC	OWN	
					Not required ¹
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Tagros Chemicals India Ltd.	PER	
			Summit Agro USA, LLC	OWN	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Tagros Chemicals India Ltd.	PER	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Tagros Chemicals India Ltd.	PER	
			Tagros Chemicals India Ltd.	PER	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Tagros Chemicals India Ltd.	PER	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	

Signature

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Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	Waiver ²
			Summit Agro USA, LLC	OWN	Waiver ³
			Summit Agro USA, LLC	OWN	
					Not required ⁴
			Summit Agro USA, LLC	OWN	
					Not required ⁵
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
					Not required ⁶
			Summit Agro USA, LLC	OWN	
					Not required ⁷
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	Waiver ⁸

Signature

Name and Title

Ann M. Tillman, Consultant

Date

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Summit Agro USA, LLC	OWN	
			Summit Agro USA, LLC	OWN	
					See 830,7840
			Summit Agro USA, LLC	PL	
				OLD	See endnote ⁹
				OLD	
				OLD	See endnote ¹⁰
				OLD	See endnote ¹¹
				OLD	See endnote ¹²
				OLD	See endnote ¹³
				OLD	See endnote ¹⁴
				OLD	See endnote ¹⁵
				OLD	See endnote ¹⁶
				OLD	
					Not required

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	See endnote ¹⁷
				OLD	
					Not required
				OLD	See endnote ¹⁸
				OLD	
				OLD	See endnote ¹⁹
				OLD	See endnote ²⁰
				OLD	
				OLD	See endnote ²¹
					Not required
				OLD	See endnote ²²
					Not required
					Not required
				OLD	Not required ²³
					Not required

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 6 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required
					Not required
					Not required
				OLD	See endnote ²⁴
					Not required
					Not required
					Not required
				OLD	See endnote ²⁵
				OLD	See endnote ²⁶
				OLD	See endnote ²⁷
				OLD	See endnote ²⁸
					Not required
			FMC Corporation	PAY	
					Not required
				OLD	See endnote ²⁹
				OLD	See endnote ³⁰

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017




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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 7 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	See endnote ³¹
				OLD	
				OLD	See endnote ³²
				OLD	
				OLD	See endnote ³³
				OLD	
					Not required
				OLD	See endnote ³⁴
				OLD	See endnote ³⁵
				OLD	See endnote ³⁶
				OLD	
				OLD	See endnote ³⁷
					Not required
					Not required
Signature 			FMC Corporation	PAY	See endnote ³⁸
			Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
					Not required
			Name and Title Ann M. Tiltman, Consultant	Date Mar. 13, 2017	



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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 8 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
			Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
			Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
					Not required

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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DATA MATRIX

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 11 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			Agricultural Reentry Task Force	OLD	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
					See 875.2100
					See 875.2100
					See 875.2100
					Not required
					Not required
					Not required

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 13 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required
					Not required
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
					See 201-1
				OLD	See endnote ⁴⁰
				OLD	
				OLD	See endnote ⁴¹
				OLD	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	See endnote ⁴²
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	See endnote ⁴³
				OLD	
				OLD	See endnote ⁴⁴
				OLD	
				OLD	See endnote ⁴⁵
				OLD	
				OLD	
				OLD	
					Not required
					Not required
					Not required

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	See endnote ⁴⁶
				OLD	See endnote ⁴⁷
				OLD	See endnote ⁴⁸
					Not required
				OLD	See endnote ⁴⁹
				OLD	
					Not required ⁵⁰
				OLD	See endnote ⁵¹
				GAP	See endnote ⁵²
				OLD	See endnote ⁵³
					Not required
					Not required
				OLD OLD OLD OLD	
					Not required
					Not required

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 18 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC Corporation	PAY	See endnote ⁵⁴
			FMC Corporation	PAY	
			FMC Corporation	PAY	
				OLD	
				OLD	
			FMC Corporation	PAY	
			FMC Corporation	PAY	
			FMC Corporation	PAY	
				OLD	
				OLD	
			FMC Corporation	PAY	
			FMC Corporation	PAY	
			FMC Corporation	PAY	
				OLD	
				OLD	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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DATA MATRIX

Date: March 13, 2017		EPA Reg No./ File Symbol: 88783-3	Page 19 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
			IR-4	PUBLIC	
			FMC Corporation	PAY	
			IR-4 IR-4	PUBLIC PUBLIC OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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DATA MATRIX

Date: March 13, 2017

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC Corporation	PAY	
				OLD	
			IR-4	PUBLIC	
				OLD	
			IR-4	PUBLIC	
				OLD	
				OLD	
			IR-4	PUBLIC	
			IR-4	PUBLIC	
				OLD	
			IR-4	PUBLIC	
			FMC Corporation	PAY	
			IR-4	PUBLIC	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017



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DATA MATRIX

Date: March 13, 2017		EPA Reg No./ File Symbol: 88783-3	Page 23 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518		Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
			IR-4	PUBLIC	
			IR-4	PUBLIC	
				OLD	
				OLD	
				OLD	
			FMC Corporation	PAY	
			IR-4	PUBLIC	
			FMC Corporation	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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DATA MATRIX

Date: March 13, 2017

EPA Reg No./ File Symbol: 88783-3

Page 24 of 29

Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
			IR-4	PUBLIC	
				OLD	
				OLD	
			IR-4	PUBLIC	
				OLD	
				OLD OLD	
			IR-4	PUBLIC	
				OLD	
				OLD	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Mar. 13, 2017




Form Approved OMB No. 2070-0060
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 25 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required
					Not required
					Not required
					Not required
					Not required

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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Form Approved OMB No. 2070-0060
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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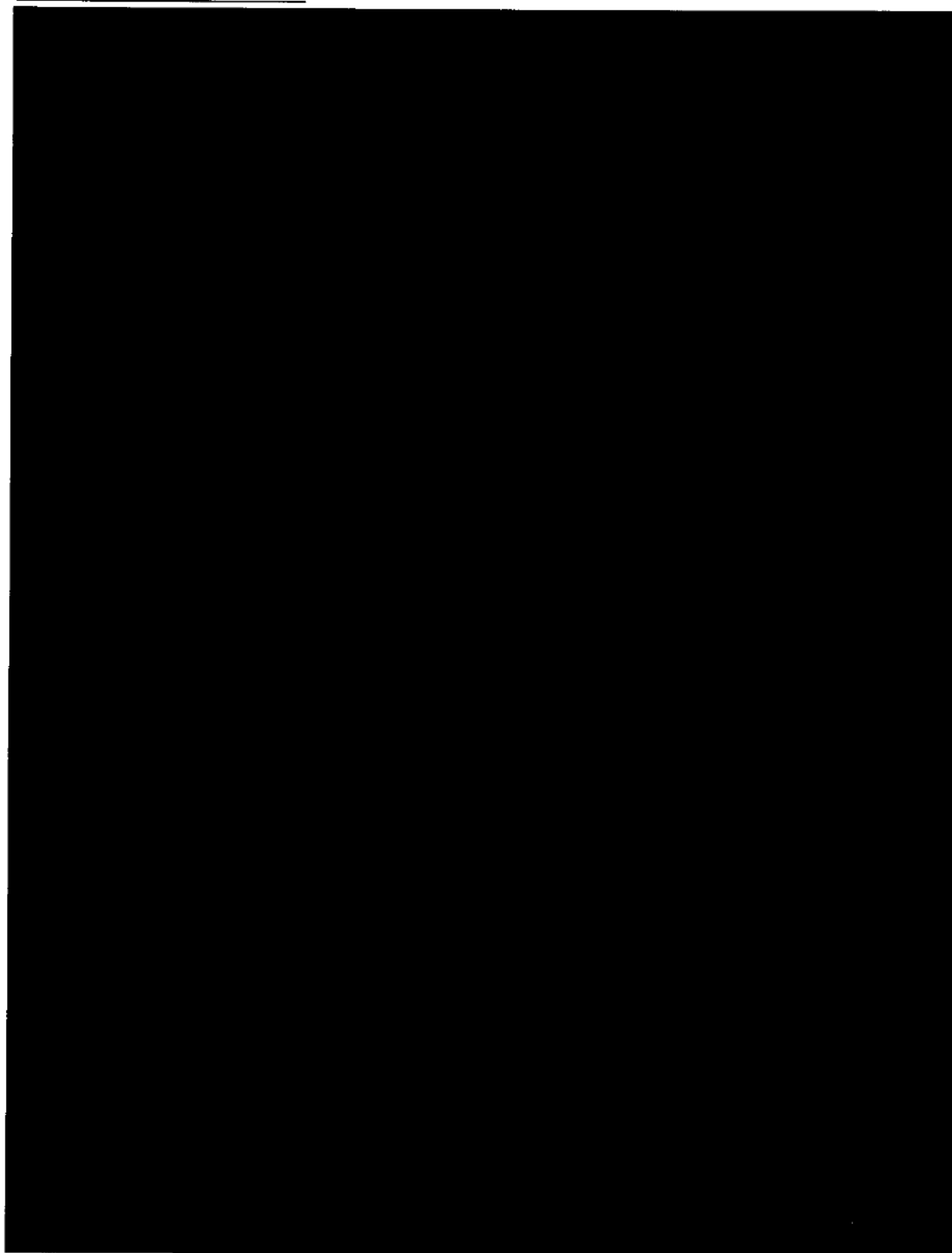
DATA MATRIX

Date: March 13, 2017	EPA Reg No./ File Symbol: 88783-3	Page 26 of 29
Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

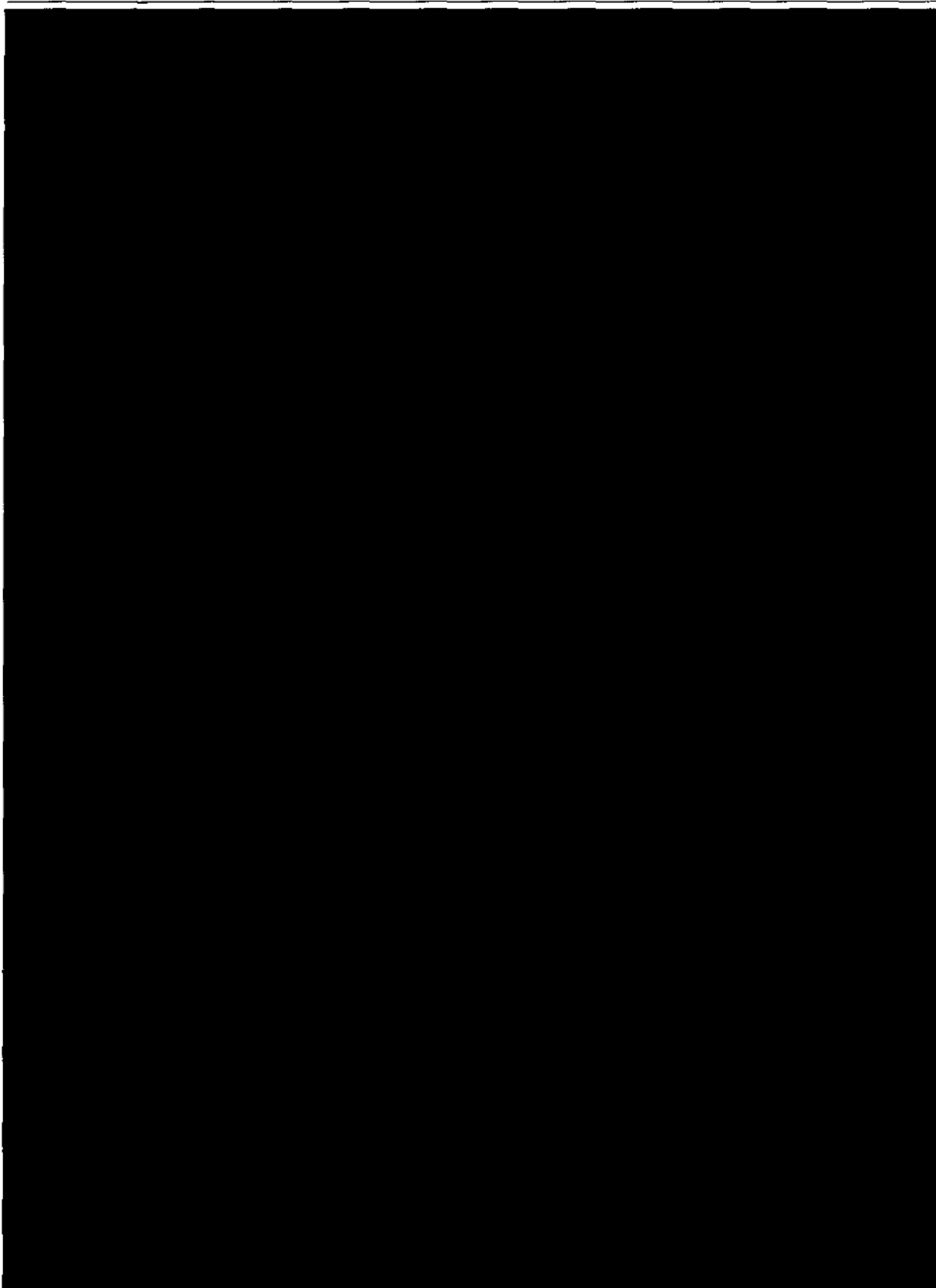
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
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				OLD	
				OLD	
				OLD	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Mar. 13, 2017
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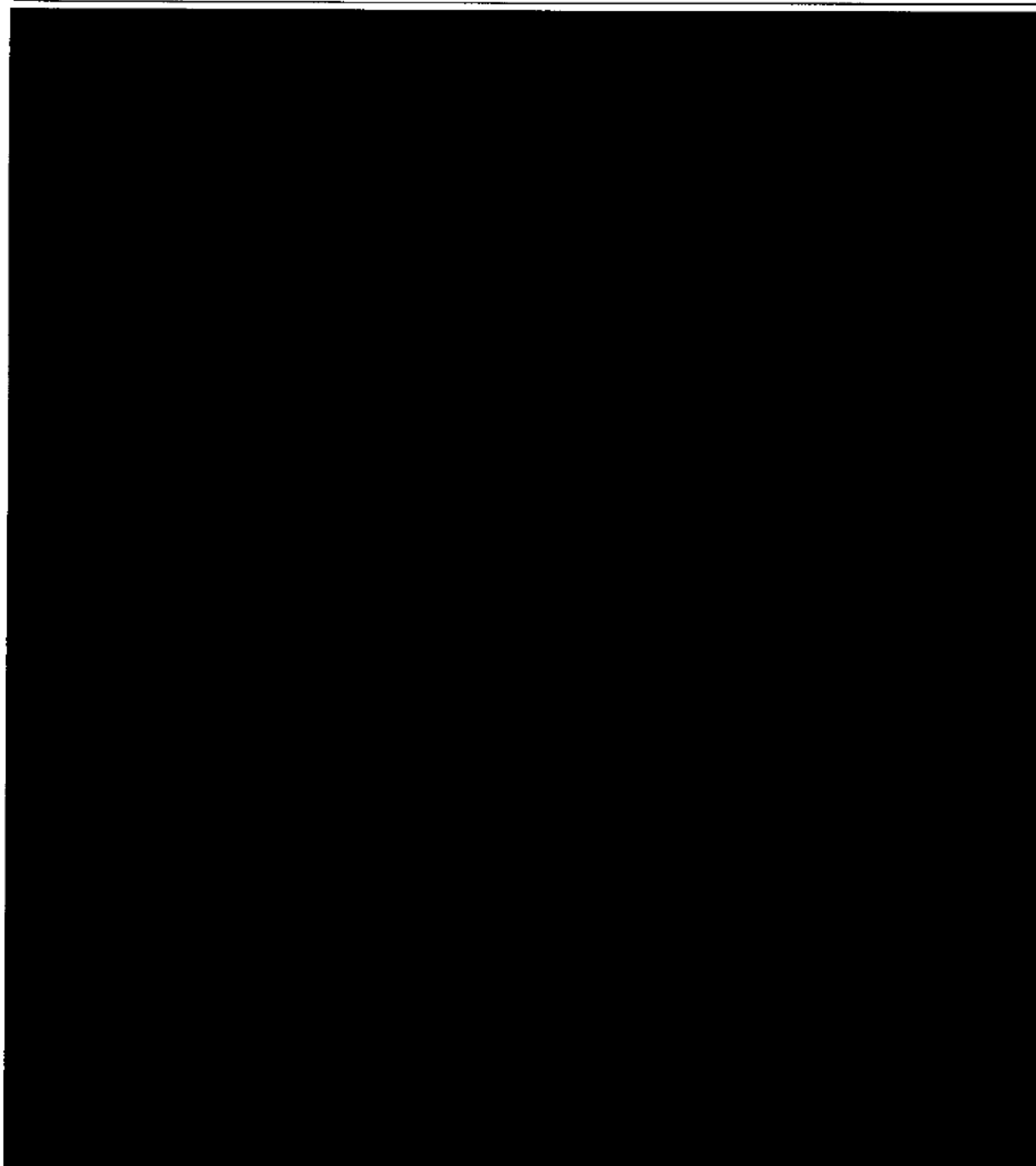
Endnotes for Data Matrix for Technical Sulfentrazone



Endnotes for Data Matrix for Technical Sulfentrazone



Endnotes for Data Matrix for Technical Sulfentrazone



PROCESSING REQUEST

Reg # 88783-3

Decision # 516013

Description: Add an unregistered source as CSF #2

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: CSF Alt #2 Dated 3/24/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Karen Samels

Division: HB/RD

Phone: (703) 347-8825

Date: 12/22/16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 12, 2016

Ms. Ann M. Tillman
Summit Agro USA, LLC
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gia Harbor, WA 98332

Subject: PRIA CSF Amendment – Amendment to add an unregistered source as an
Alternate CSF #2
Product Name: Technical Sulfentrazone
EPA Registration Number: 88783-3
Application Date: April 11, 2016
Decision Number: 516013

Dear Ms. Tillman:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/12/2012
- Alternate CSF 1 dated 01/22/2015
- Alternate CSF 2 dated 03/24/2016

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Karen Samek by phone at (703) 347-8825, or via email at samek.karen@epa.gov.

Sincerely,

A handwritten signature in black ink, which appears to read "Kathryn V. Montague". The signature is written in a cursive, flowing style.

Kathryn Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs



FEE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE: 433636; **Reg. No. /FILE SYMBOL No.:** 88783-3 (altCSF#2); **PRODUCT NAME:** Sulfentrazone Technical; **DECISION NO.:** 516013; **PC CODE(s):** 129081; **ACTION CODE:** R351; **FOOD USE:** Yes

DATE: October 18, 2016

SUBJECT: Product Chemistry Review of "Technical Sulfentrazone"

FROM: Shyam Mathur, Ph. D
Chemistry Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

S. Mathur
10-18-16
JCR

TO: Karen Samek / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

REGISTRANT: Summit Agro USA, LLC
MRID Numbers: 49885301 to 49885302

INTRODUCTION:

Pyxis Regulatory Consulting Incorporation on behalf of the applicant Summit Agro USA, has submitted an application to amend the registration of the subject product. The amendment involved the submission of the alternate CSF #2 (dated March 24, 2016) representing a revised manufacturing process. The manufacturing process was slightly modified in [REDACTED] of the process. The modified production process also used the same site as basic formulation site located at [REDACTED]. The supporting group A product chemistry data have been submitted with MRID Nos. 49885301 and 49885302. The other currently approved sites are listed below:

Alternate CSF #1 (Dated 01-22-2015; [REDACTED])
Basic CSF (dated 07-12-2012; [REDACTED])

CITAB has been asked to determine the acceptability of the proposed alt CSF #2 and the supporting product chemistry data.

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550 (product identity & composition)

The submitted data are acceptable. Active ingredient and process-related impurities were adequately described (MRID 49885301 and alt CSF#2). The nominal concentration of the active ingredient in the proposed alt CSF #2 is 94.16% which is the average derived from the 5 batch preliminary analysis, and matches with that on the product label claim of 94%. The information presented meets the data requirements for 40CFR 158.320.

DP BARCODE: 433636; **Reg. No. /FILE SYMBOL No.:** 88783-3 (altCSF#2); **PRODUCT NAME:** Sulfentrazone Technical; **DECISION NO.:** 516013; **PC CODE(s):** 129081; **ACTION CODE:** R351; **FOOD USE:** Yes

830.1600 (description of materials used to produce the product)

The product chemistry data submitted for the guideline 830.1600 (description of starting materials) are acceptable. The MSDSs of all the starting materials, and their suppliers and specifications are provided in the study with MRID 49885301. The information presented meets the data requirements for 40CFR 158.325.

830.1620 (description of production process)

The product chemistry data submitted data for the guideline 830.1620 (description of production process) are acceptable. Sulfentrazone technical was [REDACTED]. The registrant has provided description of the revised production process, flow charts, chemical reactions pathways, and quality control measures were provided in MRID 49885301. The manufacturing process has been [REDACTED]. The information presented meets the data requirements for 40CFR 158.330.

830.1670 (discussion on the formation of impurities)

The product chemistry data submitted for the guideline 830.1670 (discussion on the formation of impurities) are acceptable. Detailed information regarding the origins of impurities was provided (MRID 49885301). Potential impurities were identified and quantified as part of the five-batch analysis (MRID 49885302). The registrant has discussed the mechanism of the formation of the impurities identified in the technical product. The registrant has listed [REDACTED] identified at the concentration of >0.1%. The registrant has mentioned that there are no impurities of tox concern present in the technical produced by modified process. The information presented meets the data requirements for 40CFR 158.340.

830.1700 (preliminary analysis)

The submitted data are acceptable. Results are presented for a five-batch analysis of the active ingredient (MRID 49885302). The active ingredient sulfentrazone was identified by using HPLC-DAD-MS and identification confirmed by NMR, FTIR & UV-VIS spectroscopic validated method. The active ingredient sulfentrazone was determined by the Method No. NC2014188A (reverse phase HPLC with UV detector operating at 254 nm & external calibration). [REDACTED]

[REDACTED] The data submitted satisfy the data requirements of 40CFR§158.345.

830.1750 (certified limits)

The product chemistry data submitted for the guideline 830.1750 satisfy the data requirements of 40CFR§158.350. The registrant has proposed the nominal concentration of 94.1% for the active ingredient sulfentrazone which is also the product label claim nominal concentration. The proposed upper and lower certified limits for the A.I. are based on the standard certified limits, whereas the certified limits for the impurities are based on 5 batch analysis.

DP BARCODE: 433636; **Reg. No. /FILE SYMBOL No.:** 88783-3 (altCSF#2); **PRODUCT NAME:** Sulfentrazone Technical; **DECISION NO.:** 516013; **PC CODE(s):** 129081; **ACTION CODE:** R351; **FOOD USE:** Yes

830.1800 (enforcement analytical method)

The analytical method for quantifying the A.I. is HPLC-DAD (UV detector operating at 254 nm) with external standard calibration. The method was validated for selectivity, linearity, recovery, repeatability, LOD, LOQ (MRID 49885302). The information presented meets the data requirements for 40 CFR §158.355.

2. Group B guidelines (physical-chemical properties):

The group B product chemistry are not required for alternate CSF #2.

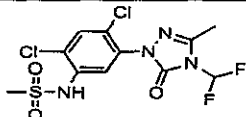
CONCLUSIONS:

The CITAB has reviewed the proposed alternate CSF #2 and the supporting group A for "Sulfentrazone Technical" has concluded that:

1. The product chemistry data submitted for guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of the production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) are acceptable. The registrant has indicated that the technical produced by revised process does not introduce any impurity which is toxicological significant. See results of 5 batch analysis on Page #22 of this report.
2. The proposed alternate CSF #2 (dated 03-24-2016; [REDACTED]) is acceptable and is supported by five batch analysis.

DP BARCODE: 433636; **Reg. No. /FILE SYMBOL No.:** 88783-3 (altCSF#2); **PRODUCT NAME:** Sulfentrazone Technical; **DECISION NO.:** 516013; **PC CODE(s):** 129081; **ACTION CODE:** R351; **FOOD USE:** Yes

830.1550. Product identity & composition: (MRID No.49885301)

Test Item:	Sulfentrazone TGA1
Classification:	Herbicide
Active Ingredient:	Sulfentrazone
Empirical Formula:	C ₁₁ H ₁₀ Cl ₂ F ₂ N ₄ O ₃ S
Molecular Weight:	387.2
CAS Registry Number:	122836-35-5
IUPAC Name:	2',4'-dichloro-5'-(4-difluoromethyl-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl)methanesulfonanilide
Structure Formula:	

DP BARCODE: 433636; Reg. No. /FILE SYMBOL No.: 88783-3 (altCSF#2); PRODUCT NAME: Sulfentrazone Technical; DECISION NO.: 516013; PC CODE(s): 129081; ACTION CODE: R351; FOOD USE: Yes

Table 1. Manufacturing and Impurity Data for "Technical Sulfentrazone"				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	49885301	A	The proposed basic CSF dated 03-24-2016 indicates NC for the AI as 94.0% as proposed. And is supported by the 5 batch analysis.
830.1600	Description of materials used to produce the product	49885301	A	MSDSs of the starting materials, and their suppliers and specifications were provided.
830.1620	Description of production process	49885301	A	Detailed description of the modified production process was provided. The technical was produced in [REDACTED]. The chemical equations, flow charts & quality control procedures for each step has been provided.
830.1670	Discussion of formation of impurities	49885301	A	The identities and origins of potential impurities were provided. There are present [REDACTED] impurities at the concentration of >0.1%. Few impurities are common to the basic CSF but there are also few new impurities identified.
830.1700	Preliminary analysis	49885302	A	Five batches of sulfentrazone technical were analyzed for determination of the A.I. and impurities. The validated HPLC/UV, UV, Proton NMR, LC-MS, were used to identify & determine the AI & the impurities. Details of the methods have been provided.
830.1750	Certified limits	Basic CSF (dated 03-24-16)	A	The lower and upper certified limit for the A.I. are within EPA's Standard Certified Limits. The certified limits for the impurities are based on the 5 batch analysis.
830.1800	Enforcement analytical method	49885302	A	The A.I. was determined using HPLC-DAD (UV detector operating at 254 nm) with external standard quantification technique. The method was validated for precision, accuracy and linearity. The method validation for all the impurities was also conducted.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

DP BARCODE: 433636; Reg. No. /FILE SYMBOL No.: 88783-3 (altCSF#2); PRODUCT NAME: Sulfentrazone Technical; DECISION NO.: 516013; PC CODE(s): 129081; ACTION CODE: R351; FOOD USE: Yes

830.1800 (enforcement analytical method)
(MRID No. 49885302)

Summary

The Sulfentrazone TGA is dissolved in Acetonitrile and separated on a SB-C18 reverse phase column. The content of Sulfentrazone is measured by an HPLC-DAD detector with an external standard quantitative method.

Chromatographic parameters

Instrument:	Agilent 1100/1200/1260 HPLC
HPLC Column:	SB-C18 150×4.6 mm, 5micron
Mobile phase:	Acetonitrile/ water(0.1%Formic acid)= 56:44
Column Temperature:	25°C
Sample size injected:	5.00 µL
Stop time:	9.00 min
Flow rate:	1 ml/min.
Signal Wavelength:	254 nm
Signal BW:	4 nm
Reference Wavelength:	360 nm
Signal BW:	100 nm
Store spectra:	None (190 nm – 400 nm, for validation of specificity)
Retention Time:	Sulfentrazone ca 4.7 min

Analysis

When the instrument gets to equilibrium, inject the blank solution. Then, inject Standard solution, Quality Control solution and Sample Solutions in the following sequence: standard solution, QC solution, four times Sample Solution, standard solution. Determine the area of the Sulfentrazone peak.

For more details please refer to MRID No. 49717501

DP BARCODE: 433636; **Reg. No. /FILE SYMBOL No.:** 88783-3 (altCSF#2); **PRODUCT NAME:** Sulfentrazone Technical; **DECISION NO.:** 516013; **PC CODE(s):** 129081; **ACTION CODE:** R351; **FOOD USE:** Yes

Calculations

Content of Sulfentrazone (%) = $(R/R') \times (W' / W) \times p \times 100$

Where:

W' - Mass of standard of the Sulfentrazone (mg);

R - Area of the Sulfentrazone peak in Sulfentrazone **TGAI** chromatograms;

W- Mass of Sulfentrazone **TGAI** (mg);

R'- Average area of Sulfentrazone peaks in the chromatogram for the 2 nearest standard injections;

p- Purity of the Sulfentrazone standard (%)

Recovery of **QC** (%) = $(\text{Measured mass for QA} / W) \times 100 = (R/R') \times (W' / W) \times 100$

Where:

W' - Mass of standard of the Sulfentrazone (mg);

R - Area of the Sulfentrazone peak in **QC** chromatograms;

W- Mass of **QC** (mg);

R'- Average area of Sulfentrazone peaks in the chromatogram for the 2 nearest standard injections;

(the last QC injection is calculated using the area of the nearest one standard injection);



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D433636; **FILE SYMBOL No.:** 88783-3 (altCSF#2 screen); **PRODUCT NAME:** Technical Sulfentrazone; **DECISION No.:** 516013; **PC Code(s):** 129081; **ACTION CODE:** R351; **FOOD Use:** Yes

DATE OUT: May 20, 2016

SUBJECT: 45/90 day screen results for Technical product "Technical Sulfentrazone"

FROM: Shyam Mathur,
Chemistry Team Leader
CITAB / RD (7505P)

SBM

TO: Karen Samek / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

Company Name: Summit Agro USA, LLC
Active Ingredient(s): Sulfentrazone (94.16%)
MRID No(s): 49885301 & 49885302

Deficiencies: No
(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

CONCLUSION:

Group A: All required Data submitted

Group B: Not required

CSF: Alternate CSF #2 (dated 03-24-2016; production site- [REDACTED]
[REDACTED] submitted.

Alternate CSF #1 (Dated 01-22-2015; [REDACTED])

Basic CSF (dated 07-12-2012; [REDACTED])

Product label: Not Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report the corrected deficiencies in response to 10 day letter. The corrected information will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4/11/16

Experts In-Processing Signature: [Signature] Date 4/12/16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>88783-3</u>		EPA Receipt Date: <u>4/11/16</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>technical and impurities only, no inerts to review</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)					X
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass / Fail
 - Required forms are complete

Inerts: N/A
 Technical and impurities only, no inerts to review.

PRN 11-3: Pass / Fail
 MRID: 498853

Overall status: Pass / Fail

SM 4/14/16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 13, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 11-APR-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. Ct. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

April 11, 2016

MRID 498853-00

ELECTRONIC SUBMISSION

Kathryn Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Summit Agro USA, LLC
Sulfentrazone Technical (EPA Reg. No. 88783-3)
Application to Add Alternate Source of Active Ingredient
PRIA Category R351

On behalf of Summit Agro USA, LLC, we are submitting an application to amend the registration of Sulfentrazone Technical to amend the manufacturing process for one of the suppliers of the active ingredient, sulfentrazone. In support of this application, we submit the following documents:

1. Application for a Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula for Alternate #2 (EPA Form 8570-4)
3. Certification with Respect to Citation of Data (EPA Form 8570-34)
4. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
5. Public File Copy of the Data Matrix (EPA Form 8570-35)
6. Copy of PRIA payment
7. Letter of Authorization
8. Product Specific Data:

MRID	Guideline Number	Study Title
49885301	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for Technical Sulfentrazone. <i>Contains Confidential Business Information.</i>
49885302	830.1700, 830.1800	Kong, L. Preliminary Analysis and Enforcement Analytical Method of Sulfentrazone TGAI—Validation of Analytical Methodology for the Assay of Related Significant Impurities and Subsequent 5-batch Analysis of Sulfentrazone TGAI. <i>Contains Confidential Business Information.</i>

Summit Agro USA, LLC is using the selective method of data support. As per EPA's interpretation of 40 CFR 152.93(b)(2)(i), Summit Agro USA, Inc. submitted notices of intent to apply and offers to pay to the extent required by FIFRA § 3(c)(1)(F). This action falls under PRIA category R351 (54: Amendment requiring data review within RD; add source of active ingredient). The fee for this action is \$13,226 and has been paid.

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman, Agent
Summit Agro USA, LLC

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: April 11, 2016

EPA Reg No./ File Symbol: 88783-3

Page 1 of 29

Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	49885301	Summit Agro USA, LLC	OWN	
		49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	49885301	Summit Agro USA, LLC	OWN	
		49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	
830.1620	Description of Production Process	49885301	Summit Agro USA, LLC	OWN	
		49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	49885301	Summit Agro USA, LLC	OWN	
830.1700	Preliminary Analysis	49059001	Tagros Chemicals India Ltd.	PER	
		48890701	Summit Agro USA, LLC	OWN	
		49885302	Summit Agro USA, LLC	OWN	
		49059002	Tagros Chemicals India Ltd.	PER	
		48890702	Summit Agro USA, LLC	OWN	

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Date

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1750	Certified Limits	49885301	Tagros Chemicals India Ltd.	PER	
		49059002	Tagros Chemicals India Ltd.	PER	
		49059001	Summit Agro USA, LLC	OWN	
		48890701			
830.1800	Enforcement Analytical Method	49885302	Summit Agro USA, LLC	OWN	
		49059002	Tagros Chemicals India Ltd.	PER	
		48890702	Summit Agro USA, LLC	OWN	
		48890703	Summit Agro USA, LLC	OWN	
830.6302	Color	48890704	Summit Agro USA, LLC	OWN	
830.6303	Physical State	48890704	Summit Agro USA, LLC	OWN	
830.6304	Odor	48890704	Summit Agro USA, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	48890704	Summit Agro USA, LLC	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	48890704	Summit Agro USA, LLC	OWN	
830.6315	Flammability	48890705	Summit Agro USA, LLC	OWN	Waiver ²
830.6316	Explodability	48890705	Summit Agro USA, LLC	OWN	Waiver ³
830.6317	Storage Stability	49267701	Summit Agro USA, LLC	OWN	
830.6319	Miscibility				Not required ⁴

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6320	Corrosion Characteristics	49267701	Summit Agro USA, LLC	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁵
830.7000	pH	48890704	Summit Agro USA, LLC	OWN	
830.7050	UV/Visible Absorption	48890704	Summit Agro USA, LLC	OWN	
830.7100	Viscosity				Not required ⁶
830.7200	Melting Point/Melting Range	48890704	Summit Agro USA, LLC	OWN	
830.7220	Boiling Point/Boiling Range				Not required ⁷
830.7300	Density/Relative Density/Bulk Density	48890704	Summit Agro USA, LLC	OWN	
830.7370	Dissociation Constants in Water	48890704	Summit Agro USA, LLC	OWN	
830.7520	Particle size, fiber length, diameter distribution	48890705	Summit Agro USA, LLC	OWN	Waiver ⁸
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				See 830.7570
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7570
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	48890704	Summit Agro USA, LLC	OWN	
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	48890704	Summit Agro USA, LLC	OWN	

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	48890704	Summit Agro USA, LLC	PL	
870.1100 (81-1)	Acute Oral Toxicity: Rat	41911605 41911606		OLD OLD	See endnote ⁹
870.1200 (81-2)	Acute Dermal Toxicity: Rat	41911607		OLD	See endnote ¹⁰
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	42471002		OLD	See endnote ¹¹
870.2400 (81-4)	Primary Eye Irritation: Rabbit	41911608		OLD	See endnote ¹²
870.2500 (81-5)	Primary Dermal Irritation	41911609		OLD	See endnote ¹³
870.2600 (81-6)	Dermal Sensitization	41911610		OLD	See endnote ¹⁴
Generic Data Requirements					
850.2100	Acute Avian Oral Toxicity	41911617		OLD	See endnote ¹⁵
850.2200	Acute Avian Dietary Toxicity	41911618 41911619		OLD OLD	See endnote ¹⁶
850.2400	Wild Mammal Toxicity				Not required
850.2300	Avian Reproductive Toxicity	43355901 43355902		OLD OLD	See endnote ¹⁷
850.2500	Simulated or Actual Field Testing				Not required

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
 8000 Regency Park, Suite 265
 Cary, NC 27518

Product:
 Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1075	Freshwater Fish Toxicity	41911620 41911621		OLD OLD	See endnote ¹⁸
850.1010	Freshwater Invertebrate Toxicity	41911622		OLD	See endnote ¹⁹
850.1025, 850.1035, 850.1045, 850.1055, 850.1075	Acute Toxicity Estuarine and Marine Organisms	43588602 44054901 43588603		OLD OLD OLD	See endnote ²⁰
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	43588605		OLD	See endnote ²¹
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)				Not required
850.1400	Fish Early Life Stage (Freshwater)	43588604		OLD	See endnote ²²
850.1400	Fish Early Life Stage (Saltwater)				Not required
850.1500	Life Cycle Fish				Not required
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	43345433		OLD	Not required ²³
850.1950	Simulated or Actual Field Testing for Aquatic Organisms				Not required
850.1735	Whole Sediment: Acute Freshwater Invertebrates				Not required
850.1740	Whole Sediment: Acute Marine Invertebrates				Not required

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Whole Sediment: Chronic Invertebrates Freshwater and Marine				Not required
850.3020	Honeybee Acute Contact Toxicity	44054902		OLD	See endnote ²⁴
850.3030	Honeybee Toxicity of Residues on Foliage				Not required
850.3040	Field Testing for Pollinators				Not required
870.6100	Delayed Neurotoxicity (Acute) – Hen				Not required
870.6200	Acute Neurotoxicity – Rat	43345405		OLD	See endnote ²⁵
870.3100	90-Day Oral: Rodent	43004601		OLD	See endnote ²⁶
870.3150	90-Day Oral: Non-Rodent	42932102		OLD	See endnote ²⁷
870.3200	21/28-Day Dermal Toxicity	44248301		OLD	See endnote ²⁸
870.3250	90-Day Dermal Toxicity				Not required
870.3465	90-Day Inhalation Toxicity	49253902	FMC Corporation	PAY	
870.6100	28-Day Delayed Neurotoxicity Hen				Not required
870.6200	90-Day Neurotoxicity	44215701		OLD	See endnote ²⁹
870.4100	Chronic Oral Rodent	43345409		OLD	See endnote ³⁰
870.4200	Carcinogenicity	43345409		OLD	See endnote ³¹
		43345407		OLD	

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3700	Reproduction/Developmental Toxicity Screening Test	42932105 42932106		OLD OLD	See endnote ³²
870.3800	2-Generation Reproduction: Rat	43345408 43869101		OLD OLD	See endnote ³³
870.6300	Developmental Neurotoxicity Study				Not required
870.5100	Bacterial Reverse Mutation Test	41911611		OLD	See endnote ³⁴
870.5300, 830.5375	<i>In vitro</i> Mammalian Cell Assay	43004604		OLD	See endnote ³⁵
870.5385, 870.5395, 870.5450	<i>In vivo</i> Cytogenetics	43004605 44248302		OLD OLD	See endnote ³⁶
870.7485	Metabolism and Pharmacokinetics	43345410		OLD	See endnote ³⁷
870.7200	Companion Animal Safety				Not required
870.7600	Dermal Penetration				Not required
870.7800	Immunotoxicity	48748601	FMC Corporation	PAY	See endnote ³⁸
875.1100	Dermal Exposure – Outdoor		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1200	Dermal Exposure - Indoor				Not required

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1300	Inhalation Exposure – Outdoor		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1500	Biological Monitoring		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1600	Data Reporting and Calculations		Agricultural Handlers Exposure Task Force	PER	See endnote ³⁹
875.1700	Product Use Information				Not required

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues	44802601		OLD	
		45005901		OLD	
		45005902		OLD	
		45005903		OLD	
		45005904		OLD	
		45005905		OLD	
		45005906		OLD	
		45005907		OLD	
		45005908		OLD	
		45005909		OLD	
		45005910		OLD	
		45005911		OLD	
		45138201		OLD	
		45138202		OLD	

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	45175101		OLD	
		45175102		OLD	
		45175103		OLD	
		45175104		OLD	
		45175105		OLD	
		45191701		OLD	
		45224801		OLD	
		45344501		OLD	
		45432301	Agricultural Reentry Task Force	PAY	
		45432302	Agricultural Reentry Task Force	PAY	
		45432303	Agricultural Reentry Task Force	PAY	
		45469501	Agricultural Reentry Task Force	PAY	
		45469502	Agricultural Reentry Task Force	PAY	
		45480301	Agricultural Reentry Task Force	PAY	
		45480302	Agricultural Reentry Task Force	PAY	
		45491901	Agricultural Reentry Task Force	PAY	
		45491902	Agricultural Reentry Task Force	PAY	
		45491903	Agricultural Reentry Task Force	PAY	
		45491904	Agricultural Reentry Task Force	PAY	
		45491905	Agricultural Reentry Task Force	PAY	

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 8000 Regency Park, Suite 265
 Cary, NC 27518

Product:
 Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	45530101	Agricultural Reentry Task Force	PAY	
		45530102	Agricultural Reentry Task Force	PAY	
		45530103	Agricultural Reentry Task Force	PAY	
		45574001	Agricultural Reentry Task Force	PAY	
		45726301	Agricultural Reentry Task Force	PAY	
		45726302	Agricultural Reentry Task Force	PAY	
		46040301	Agricultural Reentry Task Force	PAY	
		46040302	Agricultural Reentry Task Force	PAY	
		46405901	Agricultural Reentry Task Force	PAY	
		46513901	Agricultural Reentry Task Force	PAY	
		46734001	Agricultural Reentry Task Force	PAY	
		46734002	Agricultural Reentry Task Force	PAY	
		46789301	Agricultural Reentry Task Force	PAY	
		46789302	Agricultural Reentry Task Force	PAY	
		48866801	Agricultural Reentry Task Force	PAY	
		49157401	Agricultural Reentry Task Force	PAY	
		49157402	Agricultural Reentry Task Force	PAY	
		49299201	Agricultural Reentry Task Force	PAY	
		49309201	Agricultural Reentry Task Force	PAY	
		44972201		OLD	

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues (cont'd)	44972202		OLD	
		44972203		OLD	
		44972204		OLD	
		44972205		OLD	
		44972206		OLD	
		44972207		OLD	
		44983501		OLD	
		45262901		OLD	
		45262902		OLD	
		45663701	Outdoor Residential Exposure TF	PAY	
		45663702	Outdoor Residential Exposure TF	PAY	
		45663703	Outdoor Residential Exposure TF	PAY	
		46042401	Outdoor Residential Exposure TF	PAY	
		46042402	Outdoor Residential Exposure TF	PAY	
		46190501	Outdoor Residential Exposure TF	PAY	
875.2200	Soil Residue Dissipation				See 875.2100
875.2400	Dermal Exposure				See 875.2100
875.2500	Inhalation Exposure				See 875.2100
875.2600	Biological Monitoring				Not required
875.2700	Product Use Information				Not required

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
 8000 Regency Park, Suite 265
 Cary, NC 27518

Product:
 Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2800	Descriptions of Human Activity				Not required
875.2900	Data Reporting and Calculations				Not required
875.3000	Nondietary Ingestion Exposure				Not required
201-1	Droplet Size Spectrum	42565901 42608401 42907401 43254001 43485601 43485602 43485603 43485604 43493801 43493802 43508001 43535801 43535802 43657601		OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD	

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Name and Title

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Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet Size Spectrum (cont'd)	43657602		OLD	
		43665401		OLD	
		43665402		OLD	
		43757801		OLD	
		43757802		OLD	
		43766501		OLD	
		43766502		OLD	
		43766503		OLD	
		43766503		OLD	
		43766504		OLD	
		43781101		OLD	
		43803501		OLD	
		43832101		OLD	
		43832102		OLD	
		43845501		OLD	
		43845901		OLD	
		43925701		OLD	
		43953001		OLD	
		43953002		OLD	
		44010201		OLD	

Signature



Name and Title

Ann M. Tillman, Consultant

Date

April 11, 2016

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EPA Reg No./ File Symbol: 88783-3

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet size spectrum (cont'd)	44070001		OLD	
		44100901		OLD	
		44134101		OLD	
		44178701		OLD	
		44310401		OLD	
		44640801		OLD	
		44640901		OLD	
		44641001		OLD	
		44696901		OLD	
		44747401		OLD	
		44763001		OLD	
		44878601		OLD	
		44908901		OLD	
202-1	Droplet Size Spectrum				See 201-1
850.4100	Tier 1: Seedling Emergence	43345411 43783601		OLD OLD	See endnote ⁴⁰
850.4150	Tier 1: Vegetative Vigor	43345412 43783602		OLD OLD	See endnote ⁴¹

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Name and Title

Ann M. Tillman, Consultant

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400, 850.5400	Tier 1: Aquatic Plant Growth	43345413		OLD	See endnote ⁴²
		43651006		OLD	
		43651007		OLD	
		43651004		OLD	
		43651005		OLD	
850.4100	Tier 2: Seedling Emergence	43345411		OLD	See endnote ⁴³
		43783601		OLD	
850.4150	Tier 2: Vegetative Vigor	43345412		OLD	See endnote ⁴⁴
		43783602		OLD	
850.4400, 850.5400	Tier 2: Aquatic Plant Growth	43345413		OLD	See endnote ⁴⁵
		43651006		OLD	
		43651007		OLD	
		43651004		OLD	
		43651005		OLD	
850.4300	Terrestrial Field				Not required
850.4450	Aquatic Field				Not required
850.4025	Target Area Phytotoxicity				Not required

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120	Hydrolysis	41928202		OLD	See endnote ⁴⁶
835.2240	Photodegradation in Water	43588601		OLD	See endnote ⁴⁷
835.2410	Photodegradation in Soil	43345425		OLD	See endnote ⁴⁸
835.2370	Photodegradation in Air				Not required
835.4100	Aerobic Soil Metabolism	41928203 42932117		OLD OLD	See endnote ⁴⁹
835.4200	Anaerobic Soil Metabolism				Not required ⁵⁰
835.4300	Aerobic Aquatic Metabolism	43345426		OLD	See endnote ⁵¹
835.4400	Anaerobic Aquatic Metabolism			GAP	See endnote ⁵²
835.1230	Leaching/Adsorption/Desorption	43355903		OLD	See endnote ⁵³
835.1410	Volatility – Laboratory				Not required
835.8100	Volatility – Field				Not required
835.6100	Soil Field Dissipation Study	43345427 43651009 43651008 43345434		OLD OLD OLD OLD	
835.6200	Aquatic Sediment Field Dissipation Study				Not required
835.6300	Forest Field Dissipation Study				Not required

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6400	Combination and Tank Mixes				
835.7100	Ground Water Monitoring	46816001 47453601 47453602 43345434 43926814	FMC Corporation FMC Corporation FMC Corporation	PAY PAY PAY OLD OLD	See endnote ⁵⁴
850.6100	Environmental Chemistry Methods	48649401 48649402 48649403	FMC Corporation FMC Corporation FMC Corporation	PAY PAY PAY	
860.1300	Nature of the Residue: Plants	42932107 43656501 48397302 48397303 48397304	FMC Corporation FMC Corporation FMC Corporation	OLD OLD PAY PAY PAY	
860.1300	Nature of the Residue: Livestock	43345414 43345415		OLD OLD	

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC 8000 Regency Park, Suite 265 Cary, NC 27518	Product: Technical Sulfentrazone	
Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1850	Confined Rotational Crops	43761702		OLD	
		43345428		OLD	
		44450201		OLD	

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

Product:
Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Residue Analytical Methods	44450202		OLD	
		42932111		OLD	
		42932110		OLD	
		42932109		OLD	
		42932108		OLD	
		43278201		OLD	
		43651015		OLD	
		43651014		OLD	
		43761703		OLD	
		43761704		OLD	
		43761705		OLD	
		43926813		OLD	
		43926806		OLD	
		43953801		OLD	
		44005602		OLD	
		44005601		OLD	
		44118802		OLD	
		44118801		OLD	
		44450202		OLD	

Signature



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Date

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
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Product:
 Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1360	Multiresidue Method	43345417		OLD	
		43345416		OLD	
		43651013		OLD	
860.1380	Storage Stability	42932112	FMC Corporation	OLD	
		42932113		OLD	
		43345418		OLD	
		43345419		OLD	
		43345420		OLD	
		43345421		OLD	
		43761706		OLD	
		43926812		OLD	
		43926811		OLD	
860.1500	Magnitude of the Residue in Plants: Asparagus	45487902	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Berry (group 13-07)	45752601	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Berry (group 13-07)	48397309	FMC Corporation	PAY	

Signature



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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: Brassica Vegetables	47311401 47311402 45393501	IR-4 IR-4 IR-4	PUBLIC PUBLIC PUBLIC	
860.1500	Magnitude of the Residue in Plants: Citrus	48397308	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Corn	45567402	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Flax	47311407	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Horseradish	45393502	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Melon	47311403	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Mint	45393503	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Vegetable, corm and tuberous subgroup 1C	45582201	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Fruiting Vegetable	47311404 47311405	IR-4 IR-4	PUBLIC PUBLIC	
860.1500	Magnitude of the Residue in Plants: Peanuts	45077902		OLD	
860.1500	Magnitude of the Residue in Plants: Peas and Beans	45567404 47311406	FMC Corporation IR-4	PAY PUBLIC	
860.1500	Magnitude of the Residue in Plants: Pistachio	48397306	FMC Corporation	PAY	

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Magnitude of the Residue in Plants: Rhubarb	48514802	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Soybeans	42932114 42932115 43278202 43345422 43345423 44118803		OLD OLD OLD OLD OLD OLD	
860.1500	Magnitude of the Residue in Plants: Wheat	48514803	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Strawberry	47311408	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Sugarcane	45077904		OLD	
860.1500	Magnitude of the Residue in Plants: Sunflower (Subgroup 20B)	45096501	IR-4	PUBLIC	
860.1500	Magnitude of the Residue in Plants: Tobacco	44248401 44248402 44248403		OLD OLD OLD	
860.1500	Magnitude of the Residue in Plants: Tree Nuts	48397306	FMC Corporation	PAY	
860.1500	Magnitude of the Residue in Plants: Turnip	48514801	IR-4	PUBLIC	

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Applicant's/Registrant's Name and Address: Summit Agro USA, LLC
 8000 Regency Park, Suite 265
 Cary, NC 27518

Product:
 Technical Sulfentrazone

Ingredient: Sulfentrazone (CAS No. 122836-35-5)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Magnitude of the Residue in Processed Food or Feed: Citrus	48397308	FMC Corporation	PAY	
860.1520	Magnitude of the Residue in Processed Food or Feed: Corn	45567403	FMC Corporation	PAY	
860.1520	Magnitude of the Residue in Processed Food or Feed: Flax	47311407	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Mint	45393503	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Vegetable, corm and tuberous subgroup 1C	45582201	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Fruiting Vegetable	47311404	IR-4	PUBLIC	
860.1520	Magnitude of the Residue in Processed Food or Feed: Peanuts	45077903		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Soybeans	42932116 43278202		OLD OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Wheat	48514803	IR-4	PUBLIC	

Signature



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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Magnitude of the Residue in Processed Food or Feed: Sugarcane	45077905		OLD	
860.1520	Magnitude of the Residue in Processed Food or Feed: Sunflower (Group 20B)	45096501	IR-4	PUBLIC	
860.1480	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs				Not required
860.1400	Nature and Magnitude of the Residue in Potable Water				Not required
860.1400	Magnitude of the Residue in Fish				Not required
860.1400	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water				Not required
860.1460	Magnitude of the Residue in Food Handling Establishments				Not required

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Ingredient: Sulfentrazone (CAS No. 122836-35-5)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1900	Field Rotational Crops	43926803		OLD	
		43926804		OLD	
		43926805		OLD	
		43926807		OLD	
		43926808		OLD	
		43926809		OLD	
		43926810		OLD	
		44450203		OLD	
		44450205		OLD	
		44450206		OLD	
		44118807		OLD	
		44118806		OLD	
		43651012		OLD	
		44118805		OLD	
		43345431		OLD	
		44118804		OLD	
		43651010		OLD	
		44450204		OLD	

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Endnotes for Data Matrix for Technical Sulfentrazone

- ¹ **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- ² **830.6315** - Summit Agro USA, LLC requests a waiver from this data requirement because Technical Sulfentrazone is a solid and is not expected to be flammable.
- ³ **830.6316** - Summit Agro USA, LLC requests a waiver from this data requirement because sulfentrazone does not have the chemical bonds or functional groups associated with explosive chemicals.
- ⁴ **830.6319** - This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Technical Sulfentrazone is a technical material that is a solid and is not to be diluted with petroleum solvents. This data requirement is not applicable to Technical Sulfentrazone.
- ⁵ **830.6321** - These data are not required unless the product is an end-use product. Technical Sulfentrazone is a technical grade material and this data requirement is not applicable.
- ⁶ **830.7100** - This requirement is not applicable to Technical Sulfentrazone because it is a solid.
- ⁷ **830.7220** - This requirement is not applicable to Technical Sulfentrazone because it is a solid. The melting point of Technical Sulfentrazone was determined and that data is presented in MRID 48890704.
- ⁸ **830.7520** - A waiver was submitted by Summit Agro USA, LLC for this data requirement for Technical Sulfentrazone because it is not a fibrous material and is not a water-insoluble material.
- ⁹ **870.1100** - The study cited is listed in the June 5, 2014 Preliminary Human Health Risk Assessment for Registration Review (Human Health Risk Assessment, DP Barcode D410365) as satisfying the data requirement. Note MRID 41911606 was also listed under 870.1200, but this appears to be an acute oral study. As such, MRID 41911606 is also cited under 870.1100.
- ¹⁰ **870.1200** - MRID numbers 41911606 and 42286400 were listed in the Human Health Risk Assessment as satisfying this data requirement. However, MRID number 41911606 appears to correspond to an acute oral study (see 870.1100) and 42286400 appears to be a transmittal document for a response for a dermal sensitization study. Because neither of these citations correspond to an acute dermal study, MRID number 41911607 is cited.
- ¹¹ **870.1300** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹² **870.2400** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹³ **870.2500** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹⁴ **870.2600** - The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ¹⁵ **850.2100** - The study cited is listed in the June 11, 2014 Preliminary Ecological Risk Assessment for Registration Review (Ecological Risk Assessment, DP Barcode D409753) as satisfying the data requirement.
- ¹⁶ **850.2200** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ¹⁷ **850.2300** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ¹⁸ **850.1075** - The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ¹⁹ **850.1010** - The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.

Endnotes for Data Matrix for Technical Sulfentrazone

- ²⁰ **850.1025, 850.1035, 850.1045, 850.1055, 850.1075** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²¹ **850.1300** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²² **850.1400** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement.
- ²³ **850.1710, 850.1730, 850.1850** – Although based on the Koc, these data are not typically required, MRID 43345433 is cited. This study was identified as acceptable in the June 11, 2014 Ecological Risk Assessment.
- ²⁴ **850.3020** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. MRID number 43678166 is also listed in the Ecological Risk Assessment, but this study appears to correspond to an azoxystrobin study submitted by Syngenta, not a sulfentrazone study. As such, MRID 43678166 is not cited.
- ²⁵ **870.6200** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁶ **870.3100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁷ **870.3150** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁸ **870.3200** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ²⁹ **870.6200** – MRID 43345405 is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement. However, this citation corresponds to an acute neurotoxicity study. Therefore, MRID 44215701, a subchronic neurotoxicity study with sulfentrazone is cited.
- ³⁰ **870.4100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³¹ **870.4200** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³² **870.3700** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³³ **870.3800** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁴ **870.5100** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁵ **870.5300, 830.5375** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁶ **870.5385, 830.5395, 870.5450** – The studies cited are listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁷ **870.7485** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.
- ³⁸ **870.7800** – The study cited is listed in the June 5, 2014 Human Health Risk Assessment as satisfying the data requirement.

Endnotes for Data Matrix for Technical Sulfentrazone

- ³⁹ **875.1100, 875.1300, 875.1500, 875.1600** – Summit Agro USA, LLC is a “Participating Company” in good standing with the Agricultural Handlers Exposure Task Force (AHETF). Data submitted by the AHETF satisfy this data requirement. A letter of authorization for reliance on AHETF data can be provided upon request.
- ⁴⁰ **850.4100** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783601, supplement to 43345411, is also cited.
- ⁴¹ **850.4150** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783602, supplement to 43345412, is also cited.
- ⁴² **850.4400, 850.5400** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: although MRID 43651006 was classified as supplemental, EPA did not require this study to be replaced and relied on it for registration review purposes.
- ⁴³ **850.4100** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783601, supplement to 43345411, is also cited.
- ⁴⁴ **850.4150** – The study cited is listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: MRID 43783602, supplement to 43345412, is also cited.
- ⁴⁵ **850.4400, 850.5400** – The studies cited are listed in the June 11, 2014 Ecological Risk Assessment as satisfying the data requirement. Note: although MRID 43651006 was classified as supplemental, EPA did not require this study to be replaced and relied on it for registration review purposes.
- ⁴⁶ **835.2120** – The study cited is listed in the Sept. 9, 2009 EFED Problem Formulation for Registration Review (Problem Formulation) as satisfying the data requirement.
- ⁴⁷ **835.2240** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁴⁸ **835.2410** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁴⁹ **835.4100** – The studies cited are listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement. Note: it appears MRID 41922803 was listed in error and that the correct MRID should be 41928203 and is cited herein.
- ⁵⁰ **835.4200** – The study submitted was not considered acceptable in the June 11, 2014 Ecological Risk Assessment, but EPA notes that this is “not a required study” (page 31). Therefore, no data are cited here.
- ⁵¹ **835.4300** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁵² **835.4400** – The study submitted was not considered acceptable in the June 11, 2014 Ecological Risk Assessment and EPA requested the submission of additional data to satisfy the data requirement. Therefore, this data requirement is identified as “data gap.”
- ⁵³ **835.1230** – The study cited is listed in the Sept. 9, 2009 Problem Formulation as satisfying the data requirement.
- ⁵⁴ **835.7100** – The studies cited were listed in the June 11, 2014 Ecological Risk Assessment.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 12, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-516013
EPA File Symbol or Registration Number: 88783-3
Product Name: TECHNICAL SULFENTRAZONE
EPA Receipt Date: 11-Apr-2016
EPA Company Number: 88783
Company Name: SUMMIT AGRO USA, LLC

ANN TILLMAN
PYXIS REGULATORY CONSULTING, INC
SUMMIT AGRO USA, LLC
4110 136TH ST. CT. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Neresa Downs
Neresa Downs
Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

{984419D~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 23

Receipt No.

S- 984419

EPA File Symbol/Reg. No.

88783-3

Pin-Punch Date:

4/11/2016

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R351

Granted: R351

Amount Due: \$ 13,226

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Jennifer Gaines

Date: 4/12/16

Remarks:

DOCUMENTUM

Receipt for Section 3

S: 984419

Milestone Email: Ann@PyxisRC.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 88783 SUMMITAGRO USA, LLC



Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division Risk Management Team 23

Product #: 88783-3

Product Name: TECHNICAL SUBFENTRAZONE

Overseer:

Me Too
Section 3

Me Too Product
Name:

Application Date: 11-Apr-2016



OPP Rec'd Date: 11-Apr-2016



Front End Date: 11-Apr-2016



Risk Manager Send Date:



FES Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Portal submission pkg. #10913. Amendment to add unregistered source of active ingredient.

Receipt Content

Study

CSF

View/Edit

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

DOCUMENTUM

Ann Tillman

From: notification@pay.gov
Sent: April 08, 2016 1:28 PM
To: Ann Tillman
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25QUS091
Agency Tracking ID: 74992983755
Transaction Type: Sale
Transaction Date: 04/08/2016 01:28:02 PM EDT

Account Holder Name: Susan Hill

Transaction Amount: \$13,226.00
Card Type: Visa
Card Number: *****4824

Registration Number:
Company Name: Summit Agro USA LLC
Company Number: 88783
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Summit Agro USA, LLC/88783-3	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Summit Agro USA, LLC/Technical Sulfentrazone	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Summit Agro USA, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136th St. Ct. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add unregistered source of active ingredient. This application falls under PRIA Category R351 (57: Amendment adding new unregistered source). The fee has been paid (\$13,226).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) _____	PE lined fiberboard or metal drums
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 110, 55 lb		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Ann M. Tillman		Title Agent	
		Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Ann M. Tillman		5. Date April 11, 2016	
Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., ou=Pyxis, email=Ann@PyxisRC.com, c=US Date: 2016.04.11 13:55:58 -04'00'			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Summit Agro USA, LLC c/o Pyxis Reg. Consulting 4110 136th St. Ct. NW Gig Harbor, WA 253-853-7369	EPA Registration Number/File Symbol 88783-3
Active Ingredient(s) and/or representative test compound(s) sulfentrazone	Date April 11, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TGA1	Product Name Technical Sulfentrazone

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., ou=Pyxis, email=Ann@PyxisRC.com, c=US Date: 2015.04.11 13:57:49 -04'00'	Date April 11, 2016	Typed or Printed Name and Title Ann M. Tillman, Agent
--	--	------------------------	--

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

January 14, 2015

Kathryn Montague (PM23)
Document Processing Desk (**FNL LBL**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Summit Agro USA, LLC. – Technical Sulfentrazone (EPA Reg. No. 88783-3)
Submission of Final Product Labeling per the Agency Letter dated February 18, 2014

Dear Ms. Montague,

On behalf of Summit Agro USA, LLC, please find the enclosed final product labeling for Technical Sulfentrazone (EPA Reg. No. 88783-3), per the Agency letter dated Feb 6, 2013.

In support of this submission, the following documents are enclosed:

1. EPA Application Form 8570-1
2. One (1) copy of Technical Sulfentrazone final label
3. Letter of Authorization

If you have any questions or concerns, or require additional information, please contact me at (253) 853-7369 or Leanne@PyxisRC.com.

Best Regards,



P. Leanne Pruett
Pyxis Regulatory Consulting

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Summit Agro USA, LLC / 88783-3	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Summit Agro USA, LLC / Technical Sulfentrazone	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Summit Agro USA, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St., NW, Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated Feb. 18, 2014
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final printed label per the Agency letter dated Feb. 18, 2014.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	PE lined fiber-board drums
* Certification must be submitted				<input checked="" type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55 lb / 22 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name P. Leanne Pruett		Title Agent		Telephone No. (Include Area Code) 253-853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent			
4. Typed Name P. Leanne Pruett		5. Date January 12, 2015			

TECHNICAL SULFENTRAZONE

For Manufacturing of Herbicides

ACTIVE INGREDIENT	% BY WT
Sulfentrazone: N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide	94.0%
OTHER INGREDIENTS:	6.0%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Have person sip a glass of water if able to swallow.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Chemtree at 1-800-424-9300 for emergency medical treatment information 24 hrs. a day.	

Manufactured For:
Summit Agro USA, LLC
8000 Regency Park, Suite 265
Cary, NC 27518

EPA Reg. No. 88783-3
NET CONTENTS: 55.12 lb. (25 kg)

EPA Est. No. 87539-CHN-001

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Remove contaminated clothing and wash clothes before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **Only For Formulation into Herbicides Intended For The Following Uses:** Asparagus; Berry Crop group 13-07; *Brassica*, head and stem subgroup 5A; *Brassica*, leafy greens subgroup 5B; Cabbage; Citrus Crop Group 10; Dry Bean; Dry Pea; Corn, field, seed, and popcorn; Flax; Horseradish; Melon subgroup 9A; Mint; Vegetable, corm and tuberous subgroup 1C; Vegetable, fruiting subgroup 8-10; Okra; Peanuts; Pea, succulent; Pistachio; Rhubarb; Soybeans; Spring Wheat; Strawberry; Succulent Cowpea; Succulent Lima Bean; Sugarcane; Sunflower Subgroup 20B; Tobacco; Tree Nut Crop Group 14; Terrestrial Non-Crop Use; Tomato (transplanted only); Turf; Turnips; Vegetable Soybean (edamame). This product may be used to formulate end use products that have specific for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and for uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Store in original container only. Keep container closed when not in use.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into processing equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by State and local authorities. Offer the drum for recycling if available.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of Summit Agro USA, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Summit Agro USA, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither Summit Agro USA, LLC, the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

[20140218]

PRODUCT OF CHINA

175

NOT REVIEWED
In Accordance with PR Notice 82-2
Based On Draft Labeling Dated
8/6/12

